

US3392065 (Prod: Benchmark Research - Metairie - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:23:26

All time stamps listed in this document are displayed in GMT

US3392065

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 22:15:00

Generated On: 09 Jun 2021 17:23:26

Participant ID

US3392065

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

US3392065

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:09:32

Generated On: 09 Jun 2021 17:23:26

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

Visit date (dd MMM yyyy)	21 AUG 2020
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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	SCRN
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US3392065

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 03:09:31

Generated On: 09 Jun 2021 17:23:26

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	70
Age Units	YEARS
Age (Derived)	70
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 03:09:31

Generated On: 09 Jun 2021 17:23:26

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 03:09:32

Generated On: 09 Jun 2021 17:23:26

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 03:09:32

Generated On: 09 Jun 2021 17:23:26

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 20 Feb 2021 03:09:32

Generated On: 09 Jun 2021 17:23:26

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Feb 2021 03:09:32

Generated On: 09 Jun 2021 17:23:26

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN JAN 1993
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 1993
Start Year (derived)	1993
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 03:09:32

Generated On: 09 Jun 2021 17:23:26

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 03:09:32

Generated On: 09 Jun 2021 17:23:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:37 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 09:37
Height (<i>xxx.x</i>)	66.0 in
Weight (<i>xxx.x</i>)	180.6 lb
BMI (<i>xxx.x</i>)	29.21055 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:09:32

Generated On: 09 Jun 2021 17:23:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 20 Feb 2021 03:09:31

Generated On: 09 Jun 2021 17:23:26

Date of assessment (*dd MMM yyyy*) 21 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN JAN 1993

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 03:09:32

Generated On: 09 Jun 2021 17:23:26

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 LAWYER

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 03:09:32

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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 02:48:36

Generated On: 09 Jun 2021 17:23:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 02:48:36

Generated On: 09 Jun 2021 17:23:26

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 187547

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 02:48:37

Generated On: 09 Jun 2021 17:23:26

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 02:48:37

Generated On: 09 Jun 2021 17:23:26

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)	21 AUG 2020
Time of assessment (00:00-23:59)	09:37 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 09:37
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 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 02:48:37

Generated On: 09 Jun 2021 17:23:26

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)	21 AUG 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 11:40
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 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 02:48:36

Generated On: 09 Jun 2021 17:23:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 02:48:36

Generated On: 09 Jun 2021 17:23:26

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 11:05 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 11:05

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 02:48:36

Generated On: 09 Jun 2021 17:23:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 AUG 2020
Collection time (00:00-23:59)	10:03 (24 HR)
Collection date and time (derived)	21 AUG 2020 10:03

US3392065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 02:48:35

Generated On: 09 Jun 2021 17:23:26

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:54	21 AUG 2020 09:54
Nasopharyngeal Swab 2	No		

US3392065

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:48:36

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 11:42

PC Open Date & Time

21 AUG 2020 11:25

PC Close Date & Time

21 AUG 2020 13:55

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °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	21 AUG 2020 20:56
PC Open Date & Time	21 AUG 2020 14:50
PC Close Date & Time	22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

22 AUG 2020 19:48

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

23 AUG 2020 19:49

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

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

97.1 °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):

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

24 AUG 2020 22:35

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

25 AUG 2020 23:00

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

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

97.5 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

26 AUG 2020 21:50

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

27 AUG 2020 20:32

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 8

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

28 AUG 2020 19:31

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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

21 AUG 2020 11:43

PC Open Date & Time

21 AUG 2020 11:25

PC Close Date & Time

21 AUG 2020 13:55

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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

21 AUG 2020 20:57

PC Open Date & Time

21 AUG 2020 14:50

PC Close Date & Time

22 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

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

22 AUG 2020 19:48

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

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

23 AUG 2020 19:49

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	24 AUG 2020 22:35
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

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

25 AUG 2020 23:01

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

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

26 AUG 2020 21:51

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

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

27 AUG 2020 20:32

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 11:44
PC Open Date & Time	21 AUG 2020 11:25
PC Close Date & Time	21 AUG 2020 13:55

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 20:58
PC Open Date & Time	21 AUG 2020 14:50
PC Close Date & Time	22 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☒

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 19:50
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

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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US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 19:50
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

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 ☒

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 22:36
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

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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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 23:01
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

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 ☒

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US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 21:52
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

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 ☒

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 20:33
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

28 AUG 2020 19:31

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 9

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

30 AUG 2020 00:05

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 10

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

31 AUG 2020 06:16

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 11

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

01 SEP 2020 04:39

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 12

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

01 SEP 2020 19:30

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 13

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

02 SEP 2020 20:38

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 14

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

03 SEP 2020 22:33

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 15

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

04 SEP 2020 19:12

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 16

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

06 SEP 2020 00:05

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 17

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

07 SEP 2020 02:05

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 18

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

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 19

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

08 SEP 2020 21:57

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 20

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

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 21

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

10 SEP 2020 22:27

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 22

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

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 23

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

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp 28 AUG 2020 19:32

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:23:26

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	28 AUG 2020 19:32
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 10
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	31 AUG 2020 06:16
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 11
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	01 SEP 2020 04:40
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 12
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	01 SEP 2020 19:30
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 13
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	02 SEP 2020 20:38
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 14
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	03 SEP 2020 22:33
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 15
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	04 SEP 2020 19:12
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 16
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	06 SEP 2020 00:06
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 17
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	07 SEP 2020 02:05
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 19
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	08 SEP 2020 21:57
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 21
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	10 SEP 2020 22:27
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3392065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:02:29

Generated On: 09 Jun 2021 17:23:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392065

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:02:29

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:29:09

Generated On: 09 Jun 2021 17:23:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392065

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:29:09

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:09:41

Generated On: 09 Jun 2021 17:23:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392065

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:09:41

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 04:37:27

Generated On: 09 Jun 2021 17:23:26

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	VISIT2

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 04:37:27

Generated On: 09 Jun 2021 17:23:26

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)	08:46 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 08:46
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)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 04:37:27

Generated On: 09 Jun 2021 17:23:26

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)	10:48 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 10:48
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3392065

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 04:37:27

Generated On: 09 Jun 2021 17:23:26

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.

US3392065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 04:37:27

Generated On: 09 Jun 2021 17:23:26

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) 10:17 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 10:17

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

US3392065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 04:37:27

Generated On: 09 Jun 2021 17:23:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

09:07 (24 HR)

Collection date and time (derived)

16 SEP 2020 09:07

US3392065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 04:37:27

Generated On: 09 Jun 2021 17:23:26

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	09:01	16 SEP 2020 09:01
Nasopharyngeal Swab 2	No		

US3392065

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 04:37:27

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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

98.6 °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

16 SEP 2020 10:53

PC Open Date & Time

16 SEP 2020 10:37

PC Close Date & Time

16 SEP 2020 13:07

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °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	16 SEP 2020 21:14
PC Open Date & Time	16 SEP 2020 14:02
PC Close Date & Time	17 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

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 20:52

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

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 22:06

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

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

97.4 °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

20 SEP 2020 00:15

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

20 SEP 2020 23:24

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

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

97.3 °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

22 SEP 2020 01:36

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

22 SEP 2020 20:17

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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 10:54

PC Open Date & Time

16 SEP 2020 10:37

PC Close Date & Time

16 SEP 2020 13:07

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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 21:17

PC Open Date & Time

16 SEP 2020 14:02

PC Close Date & Time

17 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

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 20:54

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

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 22:06

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

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

20 SEP 2020 00:16

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

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 23:24

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

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

22 SEP 2020 01:37

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

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 20:17

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 10:54
PC Open Date & Time	16 SEP 2020 10:37
PC Close Date & Time	16 SEP 2020 13:07

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 21:17
PC Open Date & Time	16 SEP 2020 14:02
PC Close Date & Time	17 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

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 ☒

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 20:55
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 22:07
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

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

EAB) (1725)

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US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 00:16
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

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
EAB) (1725)

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US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 23:25
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

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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US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 01:38
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 20:18
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3392065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:53:15

Generated On: 09 Jun 2021 17:23:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392065

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:53:15

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:36:52

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:36:52

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:19:15

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:19:15

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

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

Generated On: 09 Jun 2021 17:23:26

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	VISIT3

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

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

Generated On: 09 Jun 2021 17:23:26

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) _____

US3392065

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

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

Generated On: 09 Jun 2021 17:23:26

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.

US3392065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

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

Generated On: 09 Jun 2021 17:23:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 OCT 2020
Collection time (00:00-23:59)	10:03 (24 HR)
Collection date and time (derived)	12 OCT 2020 10:03

US3392065

Folder: Visit 3 Day 57 (1)

Form: Continuing

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

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 <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	21 OCT 2020 17:16:22
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 OCT 2020 16:40:19

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 NOV 2020 08:24:15
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 11:39:34

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 13:32:54
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

29 NOV 2020 06:41:37

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 15:11:19

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

15 DEC 2020 04:40:42

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 01:41:06

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

31 DEC 2020 06:16:24

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

07 JAN 2021 03:00:14

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 10:04:44
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 09:31:22

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

31 JAN 2021 05:09:05

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 FEB 2021 02:53:01
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 02:24:01

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

21 FEB 2021 06:21:10

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

28 FEB 2021 14:25:17

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 208

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	25 MAR 2021 13:24:12
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

01 APR 2021 09:28:47

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 03:18:07

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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="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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 APR 2021 00:01
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Patient Cloud Close Date & Time	29 APR 2021 23:59
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US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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°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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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°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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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°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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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="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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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°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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	28 OCT 2021 23:59
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US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

Patient Cloud Open Date & Time	05 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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°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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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°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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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°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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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°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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 MAR 2022 00:01
Patient Cloud Close Date & Time	17 MAR 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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°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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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°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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2022 00:01
Patient Cloud Close Date & Time	04 AUG 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

Patient Cloud Open Date & Time	14 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

Patient Cloud Open Date & Time	25 SEP 2022 00:01
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Patient Cloud Close Date & Time	29 SEP 2022 23:59
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US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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"/>

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

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

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3392065

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:23:26

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		27 FEB 2021 13:37:57

US3392065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:53:12

Generated On: 09 Jun 2021 17:23:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392065

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:53:12

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392065

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:15:02

Generated On: 09 Jun 2021 17:23:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392065

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:15:02

Generated On: 09 Jun 2021 17:23:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392065

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:15:02

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:15:02

Generated On: 09 Jun 2021 17:23:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:15:02

Generated On: 09 Jun 2021 17:23:26

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) _____

US3392065

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:15:02

Generated On: 09 Jun 2021 17:23:26

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.

US3392065

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:15:02

Generated On: 09 Jun 2021 17:23:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 MAR 2021

Collection time (00:00-23:59)

10:25 (24 HR)

Collection date and time (derived)

3 MAR 2021 10:25

US3392065

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:15:02

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:15:02

Generated On: 09 Jun 2021 17:23:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392065

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:15:02

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3392065

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:23:26

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3392065

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

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

Visit date (dd MMM yyyy)	11 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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US3392065

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	11 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3392065

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

Height	65 in
Weight	178 lb
BMI (xxx.x)	29.68268

US3392065

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

Height	65 in
Weight	178 lb
BMI (xxx.x)	29.68268
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)	11 JAN 2021
Time of assessment (00:00-23:59)	10:16 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 10:16
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3392065

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

Height	65 in
Weight	178 lb
BMI (xxx.x)	29.68268
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)	11 JAN 2021
Time of assessment (00:00-23:59)	12:55 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 12:55
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	169 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3392065

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

US3392065

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 JAN 2021

What was the treatment time? (00:00-23:59) 11:20 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 11:20

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

US3392065

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 JAN 2021

Collection time (00:00-23:59)

10:25 (24 HR)

Collection date and time (derived)

11 JAN 2021 10:25

US3392065

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	10:27
Collection Date and Time (derived)	11 JAN 2021 10:27

US3392065

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:15:02

Generated On: 09 Jun 2021 17:23:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392065

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:15:02

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3392065

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:15:00

Generated On: 09 Jun 2021 17:23:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 22:15:00

Generated On: 09 Jun 2021 17:23:26

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)	05 FEB 2021
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 09:30
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 22:15:00

Generated On: 09 Jun 2021 17:23:26

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)	05 FEB 2021
Time of assessment (00:00-23:59)	11:22 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 11:22
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)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3392065

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:15:00

Generated On: 09 Jun 2021 17:23:26

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.

US3392065

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 22:15:00

Generated On: 09 Jun 2021 17:23:26

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 05 FEB 2021

What was the treatment time? (00:00-23:59) 10:51 (24 HR)

Treatment Date and Time (derived) 05 FEB 2021 10:51

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

US3392065

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:15:00

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:15:02

Generated On: 09 Jun 2021 17:23:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392065

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:15:02

Generated On: 09 Jun 2021 17:23:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392065

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

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) _____

US3392065

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:15:01

Generated On: 09 Jun 2021 17:23:26

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.

US3392065

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:15:00

Generated On: 09 Jun 2021 17:23:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	3 MAR 2021
Collection time (<i>00:00-23:59</i>)	10:25 (24 HR)
Collection date and time (derived)	3 MAR 2021 10:25

US3392065

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 22:05:27

Generated On: 09 Jun 2021 17:23:26

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:05:27

Generated On: 09 Jun 2021 17:23:26

AEID

Adverse event

INJECTION SITE PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:05:27

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:05:27

Generated On: 09 Jun 2021 17:23:26

AEID

Adverse event

ACUTE DIVERTICULITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

30 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:05:27

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:05:27

Generated On: 09 Jun 2021 17:23:26

AEID	USA-US119-2021-MRNA-1273-P30 1000009
Adverse event	CHEST PAIN, UNSPECIFIED
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)	24 MAR 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)	25 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input 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)	24 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	25 MAR 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 (4)

Data signed: (b) (4) 28 Apr 2021 22:05:27

Generated On: 09 Jun 2021 17:23:26

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3392065

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:05:27

Generated On: 09 Jun 2021 17:23:26

THE SUBJECT WAS ADMITTED
TO THE EMERGENCY
DEPARTMENT WITH CHEST
PAIN. A CHEST XRAY WAS
PERFORMED AND THE SUBJECT
DID NOT UNDERGO ANY
TREATMENT DURING
ADMISSION.

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

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 22:05:27

Generated On: 09 Jun 2021 17:23:26

AEID

Adverse event

FATIGUE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

23 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 22:05:27

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

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

Yes ☒

No ☐

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

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

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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US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

	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)	22 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" 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"/>

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 243

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 (2)

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

	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)		15 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 15 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 162

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

	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)		20 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 20 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE DIVERTICULITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	30 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	07 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

Name of Medication FLAGYL

Prophylaxis Yes ☐
No ☒

Indication ACUTE DIVERTICULITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	30 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	07 FEB 2021	
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"/>

US3392065

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:23:26

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

US3392065

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:23:26

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 ☐

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

SAEID	USA-US119-2021-MRNA-1273-P301000006
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

SAEID	USA-US119-2021-MRNA-1273-P301000006
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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)	11/FEB/2021 11:44
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

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

SAEID	USA-US119-2021-MRNA-1273-P301000009
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)	2

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

SAEID	USA-US119-2021-MRNA-1273-P301000009
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)	2
Date of submission (Pre-filled from custom function)	29/MAR/2021 11:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 20:04:43

Generated On: 09 Jun 2021 17:23:26

SAEID	USA-US119-2021-MRNA-1273-P301000009
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)	2
Date of submission (Pre-filled from custom function)	19/APR/2021 06:51
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

US3392065 (Prod: Benchmark Research - Metairie - PPDS)

US3392065

Form: Participant Creation

Generated On: 09 Jun 2021 17:23:26

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'US3392065'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:30:48

US3392065

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 15:41:25

US3392065

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:30:49

US3392065

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'Clinic (Clinic)'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:41:25

US3392065

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered 'SCRN'	System	21 Aug 2020 15:41:25

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered (b) (6) 1949'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:30:50

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '70'	(b) (4)	21 Aug 2020 15:44:07
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered 'YEARS'	System	21 Aug 2020 15:44:07

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered '70'	System	21 Aug 2020 15:44:56

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Aug 2020 15:44:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 15:44:14
User entered 'Female (F)' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	21 Aug 2020 15:44:14
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 15:44:07
User entered empty.	Brandon Illickal (b) (4)	21 Aug 2020 15:44:07

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:44:07

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'I'	(b) (4)	21 Aug 2020 15:44:07

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:44:07

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:44:07

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:44:07

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:44:07

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:44:07

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered empty.	(b) (4)	21 Aug 2020 15:44:07
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:44:07

US3392065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:23:26

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:44:07

US3392065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:26

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '21 Aug 2020'	(b) (4)	21 Aug 2020 15:44:56
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered 'Aug 2020'	System	21 Aug 2020 15:44:56

US3392065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered '2020'	System	21 Aug 2020 15:44:56

US3392065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:26

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'Amendment 2 (2)'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:44:56

US3392065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 15:44:56
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:26

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered empty.	(b) (4)	21 Aug 2020 15:44:56
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered empty.	(b) (4)	21 Aug 2020 15:44:56
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'No (N)'	(b) (4)	21 Aug 2020 15:44:56
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:30:49

US3392065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:23:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered 'I'	System	21 Aug 2020 15:45:02

US3392065

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 15:45:02
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:23:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 15:45:09

US3392065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Sexual function and fertility disorders NEC, PT: Dyspareunia, LLT: Dyspareunia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:49:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:49:22
Data point term sent to Coder	System	21 Aug 2020 15:48:23
User entered 'Dyspareunia'	Brandon Illickal (b) (4)	21 Aug 2020 15:47:19

US3392065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'UN Jan 2018'	(b) (4)	21 Aug 2020 15:47:19

US3392065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:47:19

US3392065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 15:47:19
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered empty.	(b) (4)	21 Aug 2020 15:47:19

US3392065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:47:19

US3392065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered 'Jan 2018'	System	21 Aug 2020 15:47:19

US3392065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered '2018'	System	21 Aug 2020 15:47:19

US3392065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered empty.	System	21 Aug 2020 15:47:19

US3392065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered empty.	System	21 Aug 2020 15:47:19

US3392065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 20:24:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 20:24:49
Data point term sent to Coder	System	21 Sep 2020 20:23:28
User entered 'post-menopausal'	Brandon Illickal (b) (4)	21 Sep 2020 20:23:11

US3392065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'un Jan 1993'	(b) (4)	21 Sep 2020 20:23:11

US3392065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Sep 2020 20:23:11

US3392065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'Yes (Y)'	(b) (4)	21 Sep 2020 20:23:11

US3392065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered empty.	(b) (4)	21 Sep 2020 20:23:11

US3392065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Sep 2020 20:23:11

US3392065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered 'Jan 1993'	System	21 Sep 2020 20:23:11

US3392065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered '1993'	System	21 Sep 2020 20:23:11

US3392065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered empty.	System	21 Sep 2020 20:23:11

US3392065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered empty.	System	21 Sep 2020 20:23:11

US3392065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Dec 2020 16:35:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 16:35:03
Data point term sent to Coder	System	09 Dec 2020 16:33:48
User entered 'Acid Reflux'	Heather Salisbury (b) (4)	09 Dec 2020 16:32:57
	(b) (4)	

US3392065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	09 Dec 2020 16:34:09
User entered 'UN Aug 2020' reason for change: Data Entry Error	Heather Salisbury (b) (4)	09 Dec 2020 16:34:09
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	09 Dec 2020 16:33:46
User entered '22 Aug 2020' reason for change: Data Entry Error	Heather Salisbury (b) (4)	09 Dec 2020 16:33:46
User entered 'un Aug 2020'	(b) (4)	09 Dec 2020 16:32:57

US3392065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	Heather Salisbury (b) (4)	09 Dec 2020 16:32:57

US3392065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	09 Dec 2020 16:32:57

US3392065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered empty.	(b) (4) Heather Salisbury (b) (4)	09 Dec 2020 16:32:57

US3392065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	Heather Salisbury (b) (4)	09 Dec 2020 16:32:57

US3392065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered 'Aug 2020'	System	09 Dec 2020 16:32:57

US3392065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered '2020'	System	09 Dec 2020 16:32:57

US3392065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered empty.	System	09 Dec 2020 16:32:57

US3392065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered empty.	System	09 Dec 2020 16:32:57

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 15:51:39

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '21 Aug 2020'	(b) (4)	21 Aug 2020 15:51:39
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '09:37'	(b) (4)	21 Aug 2020 15:51:39

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered '21 Aug 2020 09:37'	System	21 Aug 2020 15:51:39

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '66.0' in	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:51:39
DataPoint set to visible.	System	21 Aug 2020 15:45:02

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '180.6' lb	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:51:39
DataPoint set to visible.	System	21 Aug 2020 15:45:02

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
Amendment Manager: User entered '29.21055'	System	17 Sep 2020 00:17:56
User entered '29.2'	System	21 Aug 2020 15:51:39
DataPoint set to visible.	System	21 Aug 2020 15:45:02

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered 'kg/m2'	System	21 Aug 2020 15:51:39
DataPoint set to visible.	System	21 Aug 2020 15:45:02

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 06:44:52
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	28 Sep 2020 19:30:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 19:30:22
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:15:37
User entered '98.4' F	Brandon Illickal (b) (4)	21 Aug 2020 15:51:39

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered empty; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 19:30:22
User entered 'Oral (Oral)'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:51:39

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered empty.	(b) (4)	21 Aug 2020 15:51:39

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 19:30:22
User entered '59'	Brandon Illickal (b) (4)	21 Aug 2020 15:51:39

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered 'bpm'	System	21 Aug 2020 15:51:39

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 19:30:22
User closed query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	21 Aug 2020 15:52:05
Query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	21 Aug 2020 15:52:05
User entered '14' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	21 Aug 2020 15:52:05
User opened query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	21 Aug 2020 15:51:39
User entered '59'	Brandon Illickal (b) (4)	21 Aug 2020 15:51:39

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered 'breaths/min'	System	21 Aug 2020 15:51:39

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 19:30:22
User entered '158'	Brandon Illickal (b) (4)	21 Aug 2020 15:51:39

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered 'mmHg'	System	21 Aug 2020 15:51:39

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 19:30:22
User entered '94'	Brandon Illickal (b) (4)	21 Aug 2020 15:51:39

US3392065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User entered 'mmHg'	System	21 Aug 2020 15:51:39

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23

US3392065

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 15:47:28
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	30 Sep 2020 21:04:05
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 14:25:50
User entered '21 Aug 2020'	Brandon Illickal (b) (4)	21 Aug 2020 15:47:28

US3392065

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:26

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Aug 2020 15:48:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 15:48:06
User entered '21 Aug 2020' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	21 Aug 2020 15:48:06
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 15:47:34
User entered empty.	Brandon Illickal (b) (4)	21 Aug 2020 15:47:34

US3392065

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'No (N)'	(b) (4)	21 Aug 2020 15:47:34
	Brandon Illickal (b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:26

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 07:37:39
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	21 Sep 2020 20:22:48
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 10:06:10
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	21 Aug 2020 15:48:06
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	21 Aug 2020 15:48:06
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	21 Aug 2020 15:47:34
User entered empty.	Brandon Illickal (b) (4)	21 Aug 2020 15:47:34

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:26

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered empty.	(b) (4)	21 Aug 2020 15:47:34
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered empty.	(b) (4)	21 Aug 2020 15:47:34
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:26

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:47:34

US3392065

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'UN Jan 1993' reason for change: Per Query Resolution	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:48:06
User entered empty.	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:47:34

US3392065

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:23:26

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:47:34

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'No (N)'	(b) (4)	21 Aug 2020 15:48:43
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:48:43

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'No (N)'	(b) (4)	21 Aug 2020 15:48:43
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:48:43

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'No (N)'	(b) (4)	21 Aug 2020 15:48:43
	Brandon Illickal (b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:48:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:48:43

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:48:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

[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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:48:43

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:48:43

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:48:43

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 15:48:43

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'Lawyer'	(b) (4)	21 Aug 2020 15:48:43

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:48:43
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:48:43

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:48:43

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

[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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:48:43
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

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 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:48:43

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered 'I'	(b) (4)	21 Aug 2020 15:48:43
	Brandon Illickal (b) (4)	

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered '0'	(b) (4)	21 Aug 2020 15:48:43

US3392065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:23:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:17:23
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:09:32
User entered empty.	(b) (4)	21 Aug 2020 15:48:43
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 15:48:54

US3392065

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '21 Aug 2020'	(b) (4)	21 Aug 2020 15:48:54
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'Clinic (Clinic)'	(b) (4)	21 Aug 2020 15:48:54

US3392065

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'VISIT1'	System	21 Aug 2020 15:48:54

US3392065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 15:29:35

US3392065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '187547'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 15:29:35

US3392065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 15:29:35

US3392065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:26

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)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	21 Aug 2020 15:49:02

US3392065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:26

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)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'No (N)'	(b) (4)	21 Aug 2020 15:49:02
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'No (N)'	(b) (4)	21 Aug 2020 15:49:02
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:26

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'No (N)'	(b) (4)	21 Aug 2020 15:49:02
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:26

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'No (N)'	(b) (4)	21 Aug 2020 15:49:02
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:23:26

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 19:30:01
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:38:03
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:57:37

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:15:38
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	28 Sep 2020 19:29:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 19:29:52
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:59:52
User entered '66.0' in	Brandon Illickal (b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 19:29:52
User entered '180.6' lb	Brandon Illickal (b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:15:38
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	28 Sep 2020 19:29:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 19:29:52
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:59:52
User entered '66.0' in	Brandon Illickal (b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 19:29:52
User entered '180.6' lb	Brandon Illickal (b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User accepted default value 'Pre-Dose (PREDOSE)'	Brandon Illickal (b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Aug 2020 15:45:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 15:45:56
User entered 'Yes (Y)' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	24 Aug 2020 15:45:56
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 15:45:49
User entered empty.	Brandon Illickal (b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '21 Aug 2020'	(b) (4)	24 Aug 2020 15:45:49
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '09:37'	(b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered '21 Aug 2020 09:37'	System	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '98.4' F	(b) (4)	24 Aug 2020 15:45:49
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'Oral (Oral)'	(b) (4)	24 Aug 2020 15:45:49
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered empty.	(b) (4)	24 Aug 2020 15:45:49
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '59'	(b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'bpm'	System	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '14'	(b) (4)	24 Aug 2020 15:45:49
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'breaths/min'	System	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Aug 2020 18:19:05
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Brandon Illickal (b) (4)	24 Aug 2020 15:49:17
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	24 Aug 2020 15:45:49
User entered '158'	Brandon Illickal (b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'mmHg'	System	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '94'	(b) (4)	24 Aug 2020 15:45:49
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'mmHg'	System	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:15:38
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	28 Sep 2020 19:29:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 19:29:52
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:59:52
User entered '66.0' in	Brandon Illickal (b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 19:29:52
User entered '180.6' lb	Brandon Illickal (b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User accepted default value 'Post-Dose (POSTDOSE)'	Brandon Illickal (b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Aug 2020 15:45:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 15:45:56
User entered 'Yes (Y)' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	24 Aug 2020 15:45:56
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 15:45:49
User entered empty.	Brandon Illickal (b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '21 Aug 2020'	(b) (4)	24 Aug 2020 15:45:49
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '11:40'	(b) (4)	24 Aug 2020 15:45:49
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered '21 Aug 2020 11:40'	System	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '99.2' F	(b) (4)	24 Aug 2020 15:45:49
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'Oral (Oral)'	(b) (4)	24 Aug 2020 15:45:49
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered empty.	(b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '62'	(b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'bpm'	System	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '18'	(b) (4)	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'breaths/min'	System	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '141'	(b) (4)	24 Aug 2020 15:45:49
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'mmHg'	System	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '90'	(b) (4)	24 Aug 2020 15:45:49
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'mmHg'	System	24 Aug 2020 15:45:49

US3392065

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 15:49:15
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '21 Aug 2020'	(b) (4)	21 Aug 2020 15:49:15
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 16:13:27
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered empty.	(b) (4)	21 Aug 2020 16:13:27
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered empty.	(b) (4)	21 Aug 2020 16:13:27

US3392065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 16:13:27

US3392065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '21 Aug 2020'	(b) (4)	21 Aug 2020 16:13:27
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '11:05'	(b) (4)	21 Aug 2020 16:13:27

US3392065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered '21 Aug 2020 11:05'	System	21 Aug 2020 16:13:27

US3392065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'Left Arm (LEFT ARM)'	(b) (4)	21 Aug 2020 16:13:27

US3392065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'ONCE'	System	21 Aug 2020 16:13:27

US3392065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 16:13:27

US3392065

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 15:49:30
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '21 Aug 2020'	(b) (4)	21 Aug 2020 15:49:30
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '10:03'	(b) (4)	21 Aug 2020 15:49:30

US3392065

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered '21 Aug 2020 10:03'	System	21 Aug 2020 15:49:30

US3392065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:23:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	21 Aug 2020 15:50:08
User entered '21 Aug 2020' reason for change: Per Query Resolution	System	21 Aug 2020 15:50:08
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	Brandon Illickal (b) (4)	21 Aug 2020 15:50:08
User entered empty.		
	System	21 Aug 2020 15:50:01
	Brandon Illickal (b) (4)	21 Aug 2020 15:50:01

US3392065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brandon Illickal (b) (4)	21 Aug 2020 15:50:01

US3392065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 15:50:01
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered '09:54'	(b) (4)	21 Aug 2020 15:50:01

US3392065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered '21 Aug 2020 09:54'	System	21 Aug 2020 15:50:08
User entered empty.	System	21 Aug 2020 15:50:01

US3392065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brandon Illickal (b) (4)	21 Aug 2020 15:50:01

US3392065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'No (N)'	(b) (4)	21 Aug 2020 15:50:01
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered empty.	(b) (4)	21 Aug 2020 15:50:01
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered empty.	System	21 Aug 2020 15:50:01

US3392065

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:48:38
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 15:50:15
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'I'	System	21 Aug 2020 15:50:15

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:41:56', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '5b6122c1-e5cb-4731-b2ae-a57bc11467df'	System	21 Aug 2020 16:42:25
User entered 'Yes (Y)'	System	21 Aug 2020 16:42:25

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:42:07', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '5b6122c1-e5cb-4731-b2ae-a57bc11467df'	System	21 Aug 2020 16:42:25
User entered '99.2'	System	21 Aug 2020 16:42:25

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:42:13', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '5b6122c1-e5cb-4731-b2ae-a57bc11467df'	System	21 Aug 2020 16:42:25
User entered 'No (N)'	System	21 Aug 2020 16:42:25

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:42:21', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '5b6122c1-e5cb-4731-b2ae-a57bc11467df'	System	21 Aug 2020 16:42:25
User entered '21 Aug 2020 11:42'	System	21 Aug 2020 16:42:25

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '21 Aug 2020 11:25'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '21 Aug 2020 13:55'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:55:30', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '00a1f8bd-10a0-413d-9d82-8ae72acfb397'	System	22 Aug 2020 01:56:08
User entered 'Yes (Y)'	System	22 Aug 2020 01:56:08

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:55:42', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '00a1f8bd-10a0-413d-9d82-8ae72acfb397'	System	22 Aug 2020 01:56:08
User entered '98.1'	System	22 Aug 2020 01:56:08

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:55:47', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '00a1f8bd-10a0-413d-9d82-8ae72acfb397'	System	22 Aug 2020 01:56:08
User entered 'No (N)'	System	22 Aug 2020 01:56:08

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:56:01', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '00a1f8bd-10a0-413d-9d82-8ae72acfb397'	System	22 Aug 2020 01:56:08
User entered '21 Aug 2020 20:56'	System	22 Aug 2020 01:56:08

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '21 Aug 2020 14:50'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 2'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:46:33', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ac4f3c01-f39c-4bdb-b303-a0c92292d6d8'	System	23 Aug 2020 00:48:09
User entered 'Yes (Y)'	System	23 Aug 2020 00:48:09

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:47:20', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ac4f3c01-f39c-4bdb-b303-a0c92292d6d8'	System	23 Aug 2020 00:48:09
User entered '97.9'	System	23 Aug 2020 00:48:09

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:47:37', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ac4f3c01-f39c-4bdb-b303-a0c92292d6d8'	System	23 Aug 2020 00:48:09
User entered 'Yes (Y)'	System	23 Aug 2020 00:48:09

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
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 'Patient contacted by Cotugno,MD. Subject reports self medicating with omeprazole x 1 on day 2/3 for well localized epigastric discomfort (" stomach pain ") which she experiences on occasion. Symptoms resolved. Now asymptomatic. No other complaints conveyed.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 18:39:02
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 (ac0ceca948910bc0)', Time: '2020-08-22T19:47:56', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ac4f3c01-f39c-4bdb-b303-a0c92292d6d8'	Brandon Illickal (b) (4)	26 Aug 2020 14:59:09
User entered '1'	System	23 Aug 2020 00:48:09
	System	23 Aug 2020 00:48:09
	System	23 Aug 2020 00:48:09

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:47:56', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ac4f3c01-f39c-4bdb-b303-a0c92292d6d8'	System	23 Aug 2020 00:48:09
User entered '0'	System	23 Aug 2020 00:48:09

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:48:06', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ac4f3c01-f39c-4bdb-b303-a0c92292d6d8'	System	23 Aug 2020 00:48:09
User entered '22 Aug 2020 19:48'	System	23 Aug 2020 00:48:09

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 3'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:48:45', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'a2f17c86-f92b-46b5-85bd-91b8611bd6ec'	System	24 Aug 2020 00:49:31
User entered 'Yes (Y)'	System	24 Aug 2020 00:49:31

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:48:53', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'a2f17c86-f92b-46b5-85bd-91b8611bd6ec'	System	24 Aug 2020 00:49:31
User entered '98.3'	System	24 Aug 2020 00:49:31

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:49:08', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'a2f17c86-f92b-46b5-85bd-91b8611bd6ec'	System	24 Aug 2020 00:49:31
User entered 'Yes (Y)'	System	24 Aug 2020 00:49:31

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
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 'Patient contacted by Cotugno,MD. Subject reports self medicating with omeprazole x 1 on day 2/3 for well localized epigastric discomfort (" stomach pain ") which she experiences on occasion. Symptoms resolved. Now asymptomatic. No other complaints conveyed.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 18:39:07
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 (ac0ceca948910bc0)', Time: '2020-08-23T19:49:16', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'a2f17c86-f92b-46b5-85bd-91b8611bd6ec'	Brandon Illickal (b) (4)	26 Aug 2020 14:59:25
User entered '1'	System	24 Aug 2020 00:49:31
	System	24 Aug 2020 00:49:31
	System	24 Aug 2020 00:49:31

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:49:16', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'a2f17c86-f92b-46b5-85bd-91b8611bd6ec'	System	24 Aug 2020 00:49:31
User entered '0'	System	24 Aug 2020 00:49:31

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:49:26', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'a2f17c86-f92b-46b5-85bd-91b8611bd6ec'	System	24 Aug 2020 00:49:31
User entered '23 Aug 2020 19:49'	System	24 Aug 2020 00:49:31

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 4'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:34:22', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '588b4cc1-86d7-4de2-abf5-2f0d8fe6e92b'	System	25 Aug 2020 03:35:05
User entered 'Yes (Y)'	System	25 Aug 2020 03:35:05

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:34:39', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '588b4cc1-86d7-4de2-abf5-2f0d8fe6e92b'	System	25 Aug 2020 03:35:05
User entered '97.1'	System	25 Aug 2020 03:35:05

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:34:50', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '588b4cc1-86d7-4de2-abf5-2f0d8fe6e92b'	System	25 Aug 2020 03:35:05
User entered 'Yes (Y)'	System	25 Aug 2020 03:35:05

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:34:54', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '588b4cc1-86d7-4de2-abf5-2f0d8fe6e92b'	System	25 Aug 2020 03:35:05
User entered '0'	System	25 Aug 2020 03:35:05

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
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 'Patient contacted by Cotugno,MD. Subject reports self medicating with omeprazole x 1 on day 2/3 for well localized epigastric discomfort (" stomach pain ") which she experiences on occasion. Symptoms resolved. Now asymptomatic. No other complaints conveyed.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 18:39:13
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 (ac0ceca948910bc0)', Time: '2020-08-24T22:34:54', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '588b4cc1-86d7-4de2-abf5-2f0d8fe6e92b'	Brandon Illickal (b) (4)	26 Aug 2020 14:59:38
User entered '1'	System	25 Aug 2020 03:35:05
	System	25 Aug 2020 03:35:05
	System	25 Aug 2020 03:35:05

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:35:00', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '588b4cc1-86d7-4de2-abf5-2f0d8fe6e92b'	System	25 Aug 2020 03:35:05
User entered '24 Aug 2020 22:35'	System	25 Aug 2020 03:35:05

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 5'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:00:07', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4e6a5473-61af-4c61-a5c5-f4920662a022'	System	26 Aug 2020 04:00:46
User entered 'Yes (Y)'	System	26 Aug 2020 04:00:46

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:00:21', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4e6a5473-61af-4c61-a5c5-f4920662a022'	System	26 Aug 2020 04:00:46
User entered '97.2'	System	26 Aug 2020 04:00:46

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:00:29', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4e6a5473-61af-4c61-a5c5-f4920662a022'	System	26 Aug 2020 04:00:46
User entered 'Yes (Y)'	System	26 Aug 2020 04:00:46

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
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 'Patient contacted by Cotugno,MD. Subject reports self medicating with omeprazole x 1 on day 2/3 for well localized epigastric discomfort (" stomach pain ") which she experiences on occasion. Symptoms resolved. Now asymptomatic. No other complaints conveyed.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 18:39:19
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 (ac0ceca948910bc0)', Time: '2020-08-25T23:00:33', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4e6a5473-61af-4c61-a5c5-f4920662a022'	Brandon Illickal (b) (4)	26 Aug 2020 14:59:51
User entered '1'	System	26 Aug 2020 04:00:46
	System	26 Aug 2020 04:00:46
	System	26 Aug 2020 04:00:46

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:00:33', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4e6a5473-61af-4c61-a5c5-f4920662a022'	System	26 Aug 2020 04:00:46
User entered '0'	System	26 Aug 2020 04:00:46

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:00:40', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4e6a5473-61af-4c61-a5c5-f4920662a022'	System	26 Aug 2020 04:00:46
User entered '25 Aug 2020 23:00'	System	26 Aug 2020 04:00:46

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 6'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:50:13', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ebb724e6-97c5-4503-9562-72cecfa2ac5c'	System	27 Aug 2020 02:50:55
User entered 'Yes (Y)'	System	27 Aug 2020 02:50:55

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:50:22', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ebb724e6-97c5-4503-9562-72cecf2ac5c'	System	27 Aug 2020 02:50:55
User entered '97.5'	System	27 Aug 2020 02:50:55

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:50:38', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ebb724e6-97c5-4503-9562-72cecfa2ac5c'	System	27 Aug 2020 02:50:55
User entered 'Yes (Y)'	System	27 Aug 2020 02:50:55

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
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 'subject was contacted. medication is recorded in con meds' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 10:44:33
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).	Brandon Illickal (b) (4)	02 Sep 2020 21:55:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:50:43', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ebb724e6-97c5-4503-9562-72cecfa2ac5c'	System	27 Aug 2020 02:50:55
User entered '1'	System	27 Aug 2020 02:50:55

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:50:43', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ebb724e6-97c5-4503-9562-72cecfa2ac5c'	System	27 Aug 2020 02:50:55
User entered '0'	System	27 Aug 2020 02:50:55

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:50:50', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ebb724e6-97c5-4503-9562-72cecfa2ac5c'	System	27 Aug 2020 02:50:55
User entered '26 Aug 2020 21:50'	System	27 Aug 2020 02:50:55

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 7'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:31:34', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '702b491f-397e-4859-933a-34a63f769f6c'	System	28 Aug 2020 01:32:18
User entered 'Yes (Y)'	System	28 Aug 2020 01:32:18

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:31:44', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '702b491f-397e-4859-933a-34a63f769f6c'	System	28 Aug 2020 01:32:18
User entered '97.3'	System	28 Aug 2020 01:32:18

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:31:51', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '702b491f-397e-4859-933a-34a63f769f6c'	System	28 Aug 2020 01:32:18
User entered 'Yes (Y)'	System	28 Aug 2020 01:32:18

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
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 'subject was contacted. medication is recorded in con meds' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 10:44:38
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).	Brandon Illickal (b) (4)	02 Sep 2020 21:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:32:01', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '702b491f-397e-4859-933a-34a63f769f6c'	System	28 Aug 2020 01:32:18
User entered '1'	System	28 Aug 2020 01:32:18

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:32:01', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '702b491f-397e-4859-933a-34a63f769f6c'	System	28 Aug 2020 01:32:18
User entered '0'	System	28 Aug 2020 01:32:18

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:32:13', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '702b491f-397e-4859-933a-34a63f769f6c'	System	28 Aug 2020 01:32:18
User entered '27 Aug 2020 20:32'	System	28 Aug 2020 01:32:18

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	27 Aug 2020 02:50:55
User entered 'Day 8'	System	27 Aug 2020 02:50:55

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-28T19:30:53', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '0fb40c1a-3303-465d-b53d-692988e59c5d'	System	29 Aug 2020 00:31:13
User entered 'Yes (Y)'	System	29 Aug 2020 00:31:13

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-28T19:30:59', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '0fb40c1a-3303-465d-b53d-692988e59c5d'	System	29 Aug 2020 00:31:13
User entered '98.1'	System	29 Aug 2020 00:31:13

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-28T19:31:03', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '0fb40c1a-3303-465d-b53d-692988e59c5d'	System	29 Aug 2020 00:31:13
User entered 'No (N)'	System	29 Aug 2020 00:31:13

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-28T19:31:08', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '0fb40c1a-3303-465d-b53d-692988e59c5d'	System	29 Aug 2020 00:31:13
User entered '28 Aug 2020 19:31'	System	29 Aug 2020 00:31:13

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 02:50:55

US3392065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 02:50:55

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:42:34', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3851bf6b-3dda-4e6d-b894-6119c0db1541'	System	21 Aug 2020 16:43:19
User entered 'None (1)'	System	21 Aug 2020 16:43:19

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:42:44', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3851bf6b-3dda-4e6d-b894-6119c0db1541'	System	21 Aug 2020 16:43:19
User entered 'No (N)'	System	21 Aug 2020 16:43:19

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:42:51', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3851bf6b-3dda-4e6d-b894-6119c0db1541'	System	21 Aug 2020 16:43:19
User entered 'No (N)'	System	21 Aug 2020 16:43:19

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:43:04', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3851bf6b-3dda-4e6d-b894-6119c0db1541'	System	21 Aug 2020 16:43:19
User entered 'None (1)'	System	21 Aug 2020 16:43:19

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:43:11', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3851bf6b-3dda-4e6d-b894-6119c0db1541'	System	21 Aug 2020 16:43:19
User entered '21 Aug 2020 11:43'	System	21 Aug 2020 16:43:19

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '21 Aug 2020 11:25'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '21 Aug 2020 13:55'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:56:32', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cf7db1cf-8504-474f-ac27-53cb4dfda97e'	System	22 Aug 2020 01:57:27
User entered 'None (1)'	System	22 Aug 2020 01:57:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:56:51', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cf7db1cf-8504-474f-ac27-53cb4dfda97e'	System	22 Aug 2020 01:57:27
User entered 'No (N)'	System	22 Aug 2020 01:57:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:57:00', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cf7db1cf-8504-474f-ac27-53cb4dfda97e'	System	22 Aug 2020 01:57:27
User entered 'No (N)'	System	22 Aug 2020 01:57:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:57:14', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cf7db1cf-8504-474f-ac27-53cb4dfda97e'	System	22 Aug 2020 01:57:27
User entered 'None (1)'	System	22 Aug 2020 01:57:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:57:22', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cf7db1cf-8504-474f-ac27-53cb4dfda97e'	System	22 Aug 2020 01:57:27
User entered '21 Aug 2020 20:57'	System	22 Aug 2020 01:57:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '21 Aug 2020 14:50'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 2'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:48:14', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '1e70b91a-7796-40a6-b3d1-a433dc2e18c7'	System	23 Aug 2020 00:48:37
User entered 'None (1)'	System	23 Aug 2020 00:48:37

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:48:17', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '1e70b91a-7796-40a6-b3d1-a433dc2e18c7'	System	23 Aug 2020 00:48:37
User entered 'No (N)'	System	23 Aug 2020 00:48:37

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:48:21', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '1e70b91a-7796-40a6-b3d1-a433dc2e18c7'	System	23 Aug 2020 00:48:37
User entered 'No (N)'	System	23 Aug 2020 00:48:37

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:48:29', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '1e70b91a-7796-40a6-b3d1-a433dc2e18c7'	System	23 Aug 2020 00:48:37
User entered 'None (1)'	System	23 Aug 2020 00:48:37

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:48:33', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '1e70b91a-7796-40a6-b3d1-a433dc2e18c7'	System	23 Aug 2020 00:48:37
User entered '22 Aug 2020 19:48'	System	23 Aug 2020 00:48:37

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 3'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:49:35', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '41395ce6-40f9-43e5-87ee-49a883453aed'	System	24 Aug 2020 00:50:07
User entered 'None (1)'	System	24 Aug 2020 00:50:07

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:49:41', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '41395ce6-40f9-43e5-87ee-49a883453aed'	System	24 Aug 2020 00:50:07
User entered 'No (N)'	System	24 Aug 2020 00:50:07

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:49:47', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '41395ce6-40f9-43e5-87ee-49a883453aed'	System	24 Aug 2020 00:50:07
User entered 'No (N)'	System	24 Aug 2020 00:50:07

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:49:54', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '41395ce6-40f9-43e5-87ee-49a883453aed'	System	24 Aug 2020 00:50:07
User entered 'None (1)'	System	24 Aug 2020 00:50:07

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:49:59', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '41395ce6-40f9-43e5-87ee-49a883453aed'	System	24 Aug 2020 00:50:07
User entered '23 Aug 2020 19:49'	System	24 Aug 2020 00:50:07

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 4'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:35:07', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f8c7891a-b642-4905-a9e9-91ce307a78d0'	System	25 Aug 2020 03:35:53
User entered 'None (1)'	System	25 Aug 2020 03:35:53

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:35:11', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f8c7891a-b642-4905-a9e9-91ce307a78d0'	System	25 Aug 2020 03:35:53
User entered 'No (N)'	System	25 Aug 2020 03:35:53

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:35:31', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f8c7891a-b642-4905-a9e9-91ce307a78d0'	System	25 Aug 2020 03:35:53
User entered 'No (N)'	System	25 Aug 2020 03:35:53

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:35:40', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f8c7891a-b642-4905-a9e9-91ce307a78d0'	System	25 Aug 2020 03:35:53
User entered 'None (1)'	System	25 Aug 2020 03:35:53

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:35:46', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f8c7891a-b642-4905-a9e9-91ce307a78d0'	System	25 Aug 2020 03:35:53
User entered '24 Aug 2020 22:35'	System	25 Aug 2020 03:35:53

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 5'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:00:46', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '6db61803-5fb6-4519-a276-26340e0ddbf7'	System	26 Aug 2020 04:01:14
User entered 'None (1)'	System	26 Aug 2020 04:01:14

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:00:51', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '6db61803-5fb6-4519-a276-26340e0ddbf7'	System	26 Aug 2020 04:01:14
User entered 'No (N)'	System	26 Aug 2020 04:01:14

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:00:59', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '6db61803-5fb6-4519-a276-26340e0ddbf7'	System	26 Aug 2020 04:01:14
User entered 'No (N)'	System	26 Aug 2020 04:01:14

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:01:03', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '6db61803-5fb6-4519-a276-26340e0ddbf7'	System	26 Aug 2020 04:01:14
User entered 'None (1)'	System	26 Aug 2020 04:01:14

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:01:11', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '6db61803-5fb6-4519-a276-26340e0ddbf7'	System	26 Aug 2020 04:01:14
User entered '25 Aug 2020 23:01'	System	26 Aug 2020 04:01:14

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 6'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:50:57', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e56b7735-1ab7-4a84-8eff-64c371a87020'	System	27 Aug 2020 02:51:24
User entered 'None (1)'	System	27 Aug 2020 02:51:24

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:51:05', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e56b7735-1ab7-4a84-8eff-64c371a87020'	System	27 Aug 2020 02:51:24
User entered 'No (N)'	System	27 Aug 2020 02:51:24

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:51:12', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e56b7735-1ab7-4a84-8eff-64c371a87020'	System	27 Aug 2020 02:51:24
User entered 'No (N)'	System	27 Aug 2020 02:51:24

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:51:16', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e56b7735-1ab7-4a84-8eff-64c371a87020'	System	27 Aug 2020 02:51:24
User entered 'None (1)'	System	27 Aug 2020 02:51:24

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:51:20', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e56b7735-1ab7-4a84-8eff-64c371a87020'	System	27 Aug 2020 02:51:24
User entered '26 Aug 2020 21:51'	System	27 Aug 2020 02:51:24

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 7'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:32:22', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '55f8482c-2be5-4915-8ad0-a2cc580d35a7'	System	28 Aug 2020 01:32:58
User entered 'None (1)'	System	28 Aug 2020 01:32:58

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:32:26', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '55f8482c-2be5-4915-8ad0-a2cc580d35a7'	System	28 Aug 2020 01:32:58
User entered 'No (N)'	System	28 Aug 2020 01:32:58

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:32:34', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '55f8482c-2be5-4915-8ad0-a2cc580d35a7'	System	28 Aug 2020 01:32:58
User entered 'No (N)'	System	28 Aug 2020 01:32:58

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:32:46', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '55f8482c-2be5-4915-8ad0-a2cc580d35a7'	System	28 Aug 2020 01:32:58
User entered 'None (1)'	System	28 Aug 2020 01:32:58

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:32:53', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '55f8482c-2be5-4915-8ad0-a2cc580d35a7'	System	28 Aug 2020 01:32:58
User entered '27 Aug 2020 20:32'	System	28 Aug 2020 01:32:58

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:43:27', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '249cfe9b-7bb8-485c-89cb-eb03d14acd02'	System	21 Aug 2020 16:44:09
User entered 'None (0)'	System	21 Aug 2020 16:44:09

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:43:33', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '249cfe9b-7bb8-485c-89cb-eb03d14acd02'	System	21 Aug 2020 16:44:09
User entered 'None (0)'	System	21 Aug 2020 16:44:09

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:43:39', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '249cfe9b-7bb8-485c-89cb-eb03d14acd02'	System	21 Aug 2020 16:44:09
User entered 'None (0)'	System	21 Aug 2020 16:44:09

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:43:44', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '249cfe9b-7bb8-485c-89cb-eb03d14acd02'	System	21 Aug 2020 16:44:09
User entered 'None (0)'	System	21 Aug 2020 16:44:09

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:43:50', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '249cfe9b-7bb8-485c-89cb-eb03d14acd02'	System	21 Aug 2020 16:44:09
User entered 'None (0)'	System	21 Aug 2020 16:44:09

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:43:53', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '249cfe9b-7bb8-485c-89cb-eb03d14acd02'	System	21 Aug 2020 16:44:09
User entered 'None (0)'	System	21 Aug 2020 16:44:09

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:43:59', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '249cfe9b-7bb8-485c-89cb-eb03d14acd02'	System	21 Aug 2020 16:44:09
User entered 'No (N)'	System	21 Aug 2020 16:44:09

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T11:44:05', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '249cfe9b-7bb8-485c-89cb-eb03d14acd02'	System	21 Aug 2020 16:44:09
User entered '21 Aug 2020 11:44'	System	21 Aug 2020 16:44:09

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '21 Aug 2020 11:25'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '21 Aug 2020 13:55'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:57:34', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '16f9d329-163a-4a97-a595-d8ecff3d2e6f' User entered 'None (0)'	System	22 Aug 2020 01:58:20
	System	22 Aug 2020 01:58:20

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:57:42', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '16f9d329-163a-4a97-a595-d8ecff3d2e6f' User entered 'None (0)'	System	22 Aug 2020 01:58:20
	System	22 Aug 2020 01:58:20

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:57:49', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '16f9d329-163a-4a97-a595-d8ecff3d2e6f' User entered 'None (0)'	System	22 Aug 2020 01:58:20
	System	22 Aug 2020 01:58:20

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:57:54', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '16f9d329-163a-4a97-a595-d8ecff3d2e6f' User entered 'None (0)'	System	22 Aug 2020 01:58:20
	System	22 Aug 2020 01:58:20

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:57:59', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '16f9d329-163a-4a97-a595-d8ecff3d2e6f' User entered 'None (0)'	System	22 Aug 2020 01:58:20
	System	22 Aug 2020 01:58:20

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:58:03', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '16f9d329-163a-4a97-a595-d8ecff3d2e6f' User entered 'None (0)'	System	22 Aug 2020 01:58:20
	System	22 Aug 2020 01:58:20

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:58:11', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '16f9d329-163a-4a97-a595-d8ecff3d2e6f'	System	22 Aug 2020 01:58:20
User entered 'No (N)'	System	22 Aug 2020 01:58:20

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-21T20:58:15', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '16f9d329-163a-4a97-a595-d8ecff3d2e6f'	System	22 Aug 2020 01:58:20
User entered '21 Aug 2020 20:58'	System	22 Aug 2020 01:58:20

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '21 Aug 2020 14:50'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 2'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:48:49', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '444e5a73-b23f-481a-afb7-3bf86df671b9'	System	23 Aug 2020 00:50:05
User entered 'None (0)'	System	23 Aug 2020 00:50:05

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:48:52', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '444e5a73-b23f-481a-afb7-3bf86df671b9'	System	23 Aug 2020 00:50:05
User entered 'None (0)'	System	23 Aug 2020 00:50:05

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:48:55', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '444e5a73-b23f-481a-afb7-3bf86df671b9'	System	23 Aug 2020 00:50:05
User entered 'None (0)'	System	23 Aug 2020 00:50:05

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:49:00', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '444e5a73-b23f-481a-afb7-3bf86df671b9'	System	23 Aug 2020 00:50:05
User entered 'None (0)'	System	23 Aug 2020 00:50:05

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:49:35', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '444e5a73-b23f-481a-afb7-3bf86df671b9'	System	23 Aug 2020 00:50:05
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	23 Aug 2020 00:50:05

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:49:39', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '444e5a73-b23f-481a-afb7-3bf86df671b9'	System	23 Aug 2020 00:50:05
User entered 'None (0)'	System	23 Aug 2020 00:50:05

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:49:47', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '444e5a73-b23f-481a-afb7-3bf86df671b9'	System	23 Aug 2020 00:50:05
User entered 'No (N)'	System	23 Aug 2020 00:50:05

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-22T19:50:02', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '444e5a73-b23f-481a-afb7-3bf86df671b9'	System	23 Aug 2020 00:50:05
User entered '22 Aug 2020 19:50'	System	23 Aug 2020 00:50:05

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 3'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:50:09', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'dfa8def6-fcf7-41aa-bd0d-3de1fc71fd30'	System	24 Aug 2020 00:51:03
User entered 'None (0)'	System	24 Aug 2020 00:51:03

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:50:23', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'dfa8def6-fcf7-41aa-bd0d-3de1fc71fd30'	System	24 Aug 2020 00:51:03
User entered 'Significant; prevents daily activity (3)'	System	24 Aug 2020 00:51:03

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:50:27', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'dfa8def6-fcf7-41aa-bd0d-3de1fc71fd30'	System	24 Aug 2020 00:51:03
User entered 'None (0)'	System	24 Aug 2020 00:51:03

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:50:31', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'dfa8def6-fcf7-41aa-bd0d-3de1fc71fd30'	System	24 Aug 2020 00:51:03
User entered 'None (0)'	System	24 Aug 2020 00:51:03

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:50:42', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'dfa8def6-fcf7-41aa-bd0d-3de1fc71fd30'	System	24 Aug 2020 00:51:03
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Aug 2020 00:51:03

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:50:45', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'dfa8def6-fcf7-41aa-bd0d-3de1fc71fd30'	System	24 Aug 2020 00:51:03
User entered 'None (0)'	System	24 Aug 2020 00:51:03

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:50:49', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'dfa8def6-fcf7-41aa-bd0d-3de1fc71fd30'	System	24 Aug 2020 00:51:03
User entered 'No (N)'	System	24 Aug 2020 00:51:03

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-23T19:50:59', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'dfa8def6-fcf7-41aa-bd0d-3de1fc71fd30'	System	24 Aug 2020 00:51:03
User entered '23 Aug 2020 19:50'	System	24 Aug 2020 00:51:03

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 4'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:35:52', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f44c351f-8ee6-421b-a146-022f7522cf30'	System	25 Aug 2020 03:36:47
User entered 'None (0)'	System	25 Aug 2020 03:36:47

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:36:09', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f44c351f-8ee6-421b-a146-022f7522cf30'	System	25 Aug 2020 03:36:47
User entered 'No interference with activity (1)'	System	25 Aug 2020 03:36:47

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:36:13', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f44c351f-8ee6-421b-a146-022f7522cf30'	System	25 Aug 2020 03:36:47
User entered 'None (0)'	System	25 Aug 2020 03:36:47

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:36:17', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f44c351f-8ee6-421b-a146-022f7522cf30'	System	25 Aug 2020 03:36:47
User entered 'None (0)'	System	25 Aug 2020 03:36:47

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:36:26', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f44c351f-8ee6-421b-a146-022f7522cf30'	System	25 Aug 2020 03:36:47
User entered 'None (0)'	System	25 Aug 2020 03:36:47

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:36:30', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f44c351f-8ee6-421b-a146-022f7522cf30'	System	25 Aug 2020 03:36:47
User entered 'None (0)'	System	25 Aug 2020 03:36:47

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:36:36', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f44c351f-8ee6-421b-a146-022f7522cf30'	System	25 Aug 2020 03:36:47
User entered 'No (N)'	System	25 Aug 2020 03:36:47

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-24T22:36:44', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f44c351f-8ee6-421b-a146-022f7522cf30'	System	25 Aug 2020 03:36:47
User entered '24 Aug 2020 22:36'	System	25 Aug 2020 03:36:47

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 5'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:01:17', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3706a765-e820-4cfa-b279-5c3270f58961'	System	26 Aug 2020 04:02:00
User entered 'None (0)'	System	26 Aug 2020 04:02:00

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:01:27', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3706a765-e820-4cfa-b279-5c3270f58961'	System	26 Aug 2020 04:02:00
User entered 'No interference with activity (1)'	System	26 Aug 2020 04:02:00

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:01:31', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3706a765-e820-4cfa-b279-5c3270f58961'	System	26 Aug 2020 04:02:00
User entered 'None (0)'	System	26 Aug 2020 04:02:00

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:01:34', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3706a765-e820-4cfa-b279-5c3270f58961'	System	26 Aug 2020 04:02:00
User entered 'None (0)'	System	26 Aug 2020 04:02:00

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:01:41', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3706a765-e820-4cfa-b279-5c3270f58961'	System	26 Aug 2020 04:02:00
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	26 Aug 2020 04:02:00

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:01:45', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3706a765-e820-4cfa-b279-5c3270f58961'	System	26 Aug 2020 04:02:00
User entered 'None (0)'	System	26 Aug 2020 04:02:00

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:01:48', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3706a765-e820-4cfa-b279-5c3270f58961'	System	26 Aug 2020 04:02:00
User entered 'No (N)'	System	26 Aug 2020 04:02:00

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-25T23:01:52', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3706a765-e820-4cfa-b279-5c3270f58961'	System	26 Aug 2020 04:02:00
User entered '25 Aug 2020 23:01'	System	26 Aug 2020 04:02:00

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 6'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:51:28', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '9a9b80bc-5ccd-4739-bef7-7d75d11f10fe'	System	27 Aug 2020 02:52:13
User entered 'None (0)'	System	27 Aug 2020 02:52:13

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:51:36', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '9a9b80bc-5ccd-4739-bef7-7d75d11f10fe'	System	27 Aug 2020 02:52:13
User entered 'Some interference with activity (2)'	System	27 Aug 2020 02:52:13

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:51:40', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '9a9b80bc-5ccd-4739-bef7-7d75d11f10fe'	System	27 Aug 2020 02:52:13
User entered 'None (0)'	System	27 Aug 2020 02:52:13

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:51:44', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '9a9b80bc-5ccd-4739-bef7-7d75d11f10fe'	System	27 Aug 2020 02:52:13
User entered 'None (0)'	System	27 Aug 2020 02:52:13

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:51:50', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '9a9b80bc-5ccd-4739-bef7-7d75d11f10fe'	System	27 Aug 2020 02:52:13
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	27 Aug 2020 02:52:13

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:51:54', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '9a9b80bc-5ccd-4739-bef7-7d75d11f10fe'	System	27 Aug 2020 02:52:13
User entered 'None (0)'	System	27 Aug 2020 02:52:13

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:52:04', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '9a9b80bc-5ccd-4739-bef7-7d75d11f10fe'	System	27 Aug 2020 02:52:13
User entered 'No (N)'	System	27 Aug 2020 02:52:13

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-26T21:52:08', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '9a9b80bc-5ccd-4739-bef7-7d75d11f10fe'	System	27 Aug 2020 02:52:13
User entered '26 Aug 2020 21:52'	System	27 Aug 2020 02:52:13

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 7'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:33:05', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4f333d9c-d6f7-4420-b432-152eee28c7f0'	System	28 Aug 2020 01:33:49
User entered 'None (0)'	System	28 Aug 2020 01:33:49

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:33:11', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4f333d9c-d6f7-4420-b432-152eee28c7f0'	System	28 Aug 2020 01:33:49
User entered 'No interference with activity (1)'	System	28 Aug 2020 01:33:49

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:33:16', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4f333d9c-d6f7-4420-b432-152eee28c7f0'	System	28 Aug 2020 01:33:49
User entered 'None (0)'	System	28 Aug 2020 01:33:49

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:33:21', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4f333d9c-d6f7-4420-b432-152eee28c7f0'	System	28 Aug 2020 01:33:49
User entered 'None (0)'	System	28 Aug 2020 01:33:49

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:33:28', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4f333d9c-d6f7-4420-b432-152eee28c7f0'	System	28 Aug 2020 01:33:49
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	28 Aug 2020 01:33:49

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:33:32', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4f333d9c-d6f7-4420-b432-152eee28c7f0'	System	28 Aug 2020 01:33:49
User entered 'None (0)'	System	28 Aug 2020 01:33:49

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:33:36', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4f333d9c-d6f7-4420-b432-152eee28c7f0'	System	28 Aug 2020 01:33:49
User entered 'No (N)'	System	28 Aug 2020 01:33:49

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-27T20:33:44', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4f333d9c-d6f7-4420-b432-152eee28c7f0'	System	28 Aug 2020 01:33:49
User entered '27 Aug 2020 20:33'	System	28 Aug 2020 01:33:49

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	27 Aug 2020 02:52:13
User entered 'Day 8'	System	27 Aug 2020 02:52:13

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-28T19:31:31', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '93556343-9571-4d05-9ba7-a6942224ac47'	System	29 Aug 2020 00:31:59
User entered 'No interference with activity (1)'	System	29 Aug 2020 00:31:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-28T19:31:54', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '93556343-9571-4d05-9ba7-a6942224ac47'	System	29 Aug 2020 00:31:59
User entered '28 Aug 2020 19:31'	System	29 Aug 2020 00:31:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 02:52:13

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 02:52:13

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	28 Aug 2020 01:33:49
User entered 'Day 9'	System	28 Aug 2020 01:33:49

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-30T00:04:58', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '9fc0d7d1-c666-4874-b1cf-34b3f88dad6d'	System	30 Aug 2020 05:05:11
User entered 'Some interference with activity (2)'	System	30 Aug 2020 05:05:11

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-30T00:05:07', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '9fc0d7d1-c666-4874-b1cf-34b3f88dad6d'	System	30 Aug 2020 05:05:11
User entered '30 Aug 2020 00:05'	System	30 Aug 2020 05:05:11

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 01:33:49

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 01:33:49

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	29 Aug 2020 00:31:59
User entered 'Day 10'	System	29 Aug 2020 00:31:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-31T06:16:16', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'a319b45f-a5b6-47c7-904d-e20e1a9fb020'	System	31 Aug 2020 11:16:27
User entered 'No interference with activity (1)'	System	31 Aug 2020 11:16:27

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-31T06:16:24', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'a319b45f-a5b6-47c7-904d-e20e1a9fb020'	System	31 Aug 2020 11:16:27
User entered '31 Aug 2020 06:16'	System	31 Aug 2020 11:16:27

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 00:31:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 00:31:59

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	30 Aug 2020 05:05:11
User entered 'Day 11'	System	30 Aug 2020 05:05:11

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-01T04:39:48', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd438a843-41a9-4aa4-8470-7f9b0c7b0fde'	System	01 Sep 2020 09:39:58
User entered 'No interference with activity (1)'	System	01 Sep 2020 09:39:58

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-01T04:39:56', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd438a843-41a9-4aa4-8470-7f9b0c7b0fde'	System	01 Sep 2020 09:39:58
User entered '01 Sep 2020 04:39'	System	01 Sep 2020 09:39:58

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 05:05:11

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 05:05:11

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	31 Aug 2020 11:16:27
User entered 'Day 12'	System	31 Aug 2020 11:16:27

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-01T19:30:16', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '23bd76a9-bfc3-49ed-afe1-1cf46055b4b6'	System	02 Sep 2020 00:30:25
User entered 'No interference with activity (1)'	System	02 Sep 2020 00:30:25

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-01T19:30:22', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '23bd76a9-bfc3-49ed-afe1-1cf46055b4b6'	System	02 Sep 2020 00:30:25
User entered '01 Sep 2020 19:30'	System	02 Sep 2020 00:30:25

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 11:16:27

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 11:16:27

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	01 Sep 2020 09:39:58
User entered 'Day 13'	System	01 Sep 2020 09:39:58

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-02T20:38:06', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '2c947a7c-0969-4ab2-ab94-7ff552feb534'	System	03 Sep 2020 01:38:26
User entered 'Some interference with activity (2)'	System	03 Sep 2020 01:38:26

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-02T20:38:12', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '2c947a7c-0969-4ab2-ab94-7ff552feb534'	System	03 Sep 2020 01:38:26
User entered '02 Sep 2020 20:38'	System	03 Sep 2020 01:38:26

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 09:39:58

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 09:39:58

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	02 Sep 2020 00:30:25
User entered 'Day 14'	System	02 Sep 2020 00:30:25

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-03T22:33:28', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '44c05543-6480-4080-9dc6-3b61635b45d2'	System	04 Sep 2020 03:33:37
User entered 'No interference with activity (1)'	System	04 Sep 2020 03:33:37

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-03T22:33:31', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '44c05543-6480-4080-9dc6-3b61635b45d2'	System	04 Sep 2020 03:33:37
User entered '03 Sep 2020 22:33'	System	04 Sep 2020 03:33:37

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 00:30:25

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 00:30:25

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	03 Sep 2020 01:38:26
User entered 'Day 15'	System	03 Sep 2020 01:38:26

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-04T19:12:41', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ffb62ebb-5131-41e2-bfea-879e58311dd7'	System	05 Sep 2020 00:12:51
User entered 'No interference with activity (1)'	System	05 Sep 2020 00:12:51

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-04T19:12:46', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ffb62ebb-5131-41e2-bfea-879e58311dd7'	System	05 Sep 2020 00:12:51
User entered '04 Sep 2020 19:12'	System	05 Sep 2020 00:12:51

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 01:38:26

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 01:38:26

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	04 Sep 2020 03:33:37
User entered 'Day 16'	System	04 Sep 2020 03:33:37

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-06T00:05:47', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd63082d6-0d9c-4172-820f-669f77699931'	System	06 Sep 2020 05:05:56
User entered 'Some interference with activity (2)'	System	06 Sep 2020 05:05:56

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-06T00:05:53', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd63082d6-0d9c-4172-820f-669f77699931'	System	06 Sep 2020 05:05:56
User entered '06 Sep 2020 00:05'	System	06 Sep 2020 05:05:56

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 03:33:37

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 03:33:37

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	05 Sep 2020 00:12:51
User entered 'Day 17'	System	05 Sep 2020 00:12:51

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-07T02:05:12', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'c7b65d44-76ca-47a5-9d0a-fd0869ba0e8b'	System	07 Sep 2020 07:05:20
User entered 'No interference with activity (1)'	System	07 Sep 2020 07:05:20

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-07T02:05:16', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'c7b65d44-76ca-47a5-9d0a-fd0869ba0e8b'	System	07 Sep 2020 07:05:20
User entered '07 Sep 2020 02:05'	System	07 Sep 2020 07:05:20

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 00:12:51

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 00:12:51

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	06 Sep 2020 05:05:56
User entered 'Day 18'	System	06 Sep 2020 05:05:56

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 05:05:56

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 05:05:56

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	07 Sep 2020 07:05:20
User entered 'Day 19'	System	07 Sep 2020 07:05:20

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-08T21:57:12', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '2ab9a9b3-d49d-434f-8e7a-865e404901c7'	System	09 Sep 2020 02:57:21
User entered 'No interference with activity (1)'	System	09 Sep 2020 02:57:21

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-08T21:57:16', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '2ab9a9b3-d49d-434f-8e7a-865e404901c7'	System	09 Sep 2020 02:57:21
User entered '08 Sep 2020 21:57'	System	09 Sep 2020 02:57:21

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 07:05:20

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 07:05:20

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	09 Sep 2020 02:57:21
User entered 'Day 20'	System	09 Sep 2020 02:57:21

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 02:57:21

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 02:57:21

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	09 Sep 2020 02:57:21
User entered 'Day 21'	System	09 Sep 2020 02:57:21

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-10T22:27:30', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e201b319-eb3b-432a-b352-b431a3528d7a'	System	11 Sep 2020 03:27:40
User entered 'No interference with activity (1)'	System	11 Sep 2020 03:27:40

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-10T22:27:34', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e201b319-eb3b-432a-b352-b431a3528d7a'	System	11 Sep 2020 03:27:40
User entered '10 Sep 2020 22:27'	System	11 Sep 2020 03:27:40

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 02:57:21

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 02:57:21

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	11 Sep 2020 03:27:40
User entered 'Day 22'	System	11 Sep 2020 03:27:40

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '11 Sep 2020 12:00'	System	11 Sep 2020 03:27:40

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 03:27:40

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	11 Sep 2020 03:27:40
User entered 'Day 23'	System	11 Sep 2020 03:27:40

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 03:27:40

US3392065

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 03:27:40

US3392065

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	27 Aug 2020 02:52:13
User entered 'Day 8'	System	27 Aug 2020 02:52:13

US3392065

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:23:26

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-28T19:31:59', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'c30827e8-bde7-4bd0-ab31-fcd4f347a9f4'	System	29 Aug 2020 00:32:10
User entered 'None (0)'	System	29 Aug 2020 00:32:10

US3392065

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-28T19:32:04', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'c30827e8-bde7-4bd0-ab31-fcd4f347a9f4'	System	29 Aug 2020 00:32:10
User entered '28 Aug 2020 19:32'	System	29 Aug 2020 00:32:10

US3392065

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 02:52:13

US3392065

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 02:52:13

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	27 Aug 2020 02:50:55
User entered 'Day 8'	System	27 Aug 2020 02:50:55

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-28T19:32:13', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '59ba8b25-b19b-4c4c-93da-a1ad67a3aa4b'	System	29 Aug 2020 00:32:22
User entered 'No (N)'	System	29 Aug 2020 00:32:22

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-28T19:32:17', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '59ba8b25-b19b-4c4c-93da-a1ad67a3aa4b'	System	29 Aug 2020 00:32:22
User entered '28 Aug 2020 19:32'	System	29 Aug 2020 00:32:22

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 02:50:55

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 02:50:55

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	29 Aug 2020 00:31:59
User entered 'Day 10'	System	29 Aug 2020 00:31:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-31T06:16:37', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '0c5d9a76-5d0f-47f0-ab88-07c5787f0193'	System	31 Aug 2020 11:16:45
User entered 'No (N)'	System	31 Aug 2020 11:16:45

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-08-31T06:16:42', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '0c5d9a76-5d0f-47f0-ab88-07c5787f0193'	System	31 Aug 2020 11:16:45
User entered '31 Aug 2020 06:16'	System	31 Aug 2020 11:16:45

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 00:31:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 00:31:59

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	30 Aug 2020 05:05:11
User entered 'Day 11'	System	30 Aug 2020 05:05:11

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-01T04:40:10', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '42a475ce-54a1-4eef-8551-031989077c8c'	System	01 Sep 2020 09:40:16
User entered 'No (N)'	System	01 Sep 2020 09:40:16

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-01T04:40:14', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '42a475ce-54a1-4eef-8551-031989077c8c'	System	01 Sep 2020 09:40:16
User entered '01 Sep 2020 04:40'	System	01 Sep 2020 09:40:16

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 05:05:11

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 05:05:11

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	31 Aug 2020 11:16:27
User entered 'Day 12'	System	31 Aug 2020 11:16:27

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-01T19:30:31', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '9e0d593f-e97b-49e8-bd05-b243bb143947'	System	02 Sep 2020 00:30:41
User entered 'No (N)'	System	02 Sep 2020 00:30:41

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-01T19:30:36', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '9e0d593f-e97b-49e8-bd05-b243bb143947'	System	02 Sep 2020 00:30:41
User entered '01 Sep 2020 19:30'	System	02 Sep 2020 00:30:41

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 11:16:27

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 11:16:27

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	01 Sep 2020 09:39:58
User entered 'Day 13'	System	01 Sep 2020 09:39:58

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-02T20:38:21', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '39fc35d6-cc75-42b4-8cac-c6ebd055bacc'	System	03 Sep 2020 01:38:28
User entered 'No (N)'	System	03 Sep 2020 01:38:28

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-02T20:38:25', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '39fc35d6-cc75-42b4-8cac-c6ebd055bacc'	System	03 Sep 2020 01:38:28
User entered '02 Sep 2020 20:38'	System	03 Sep 2020 01:38:28

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 09:39:58

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 09:39:58

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	02 Sep 2020 00:30:25
User entered 'Day 14'	System	02 Sep 2020 00:30:25

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-03T22:33:41', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'adda0b26-93a1-44f1-b20b-4a04d898f8c3'	System	04 Sep 2020 03:33:51
User entered 'No (N)'	System	04 Sep 2020 03:33:51

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-03T22:33:44', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'adda0b26-93a1-44f1-b20b-4a04d898f8c3'	System	04 Sep 2020 03:33:51
User entered '03 Sep 2020 22:33'	System	04 Sep 2020 03:33:51

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 00:30:25

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 00:30:25

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	03 Sep 2020 01:38:26
User entered 'Day 15'	System	03 Sep 2020 01:38:26

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-04T19:12:53', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '41aeccfd-39b3-4499-97aa-ce3a54c30e1a'	System	05 Sep 2020 00:13:00
User entered 'No (N)'	System	05 Sep 2020 00:13:00

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-04T19:12:57', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '41aeccfd-39b3-4499-97aa-ce3a54c30e1a'	System	05 Sep 2020 00:13:00
User entered '04 Sep 2020 19:12'	System	05 Sep 2020 00:13:00

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 01:38:26

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 01:38:26

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	04 Sep 2020 03:33:37
User entered 'Day 16'	System	04 Sep 2020 03:33:37

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-06T00:06:02', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '879b94bd-98c2-4360-a062-4a5f13a9997f'	System	06 Sep 2020 05:06:12
User entered 'No (N)'	System	06 Sep 2020 05:06:12

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-06T00:06:06', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '879b94bd-98c2-4360-a062-4a5f13a9997f'	System	06 Sep 2020 05:06:12
User entered '06 Sep 2020 00:06'	System	06 Sep 2020 05:06:12

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 03:33:37

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 03:33:37

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	05 Sep 2020 00:12:51
User entered 'Day 17'	System	05 Sep 2020 00:12:51

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-07T02:05:21', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '729f17e2-0f2e-47ce-8a26-175e69a93075'	System	07 Sep 2020 07:05:31
User entered 'No (N)'	System	07 Sep 2020 07:05:31

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-07T02:05:25', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '729f17e2-0f2e-47ce-8a26-175e69a93075'	System	07 Sep 2020 07:05:31
User entered '07 Sep 2020 02:05'	System	07 Sep 2020 07:05:31

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 00:12:51

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 00:12:51

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	06 Sep 2020 05:05:56
User entered 'Day 18'	System	06 Sep 2020 05:05:56

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 05:05:56

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 05:05:56

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	07 Sep 2020 07:05:20
User entered 'Day 19'	System	07 Sep 2020 07:05:20

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-08T21:57:24', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '318ae4e1-5922-4bfb-be82-e779527c117c'	System	09 Sep 2020 02:57:31
User entered 'No (N)'	System	09 Sep 2020 02:57:31

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-08T21:57:27', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '318ae4e1-5922-4bfb-be82-e779527c117c'	System	09 Sep 2020 02:57:31
User entered '08 Sep 2020 21:57'	System	09 Sep 2020 02:57:31

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 07:05:20

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 07:05:20

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	09 Sep 2020 02:57:21
User entered 'Day 20'	System	09 Sep 2020 02:57:21

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 02:57:21

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 02:57:21

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	09 Sep 2020 02:57:21
User entered 'Day 21'	System	09 Sep 2020 02:57:21

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-10T22:27:46', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '8d301cad-8561-4cda-861a-45fbceb86461'	System	11 Sep 2020 03:27:51
User entered 'No (N)'	System	11 Sep 2020 03:27:51

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-10T22:27:48', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '8d301cad-8561-4cda-861a-45fbceb86461'	System	11 Sep 2020 03:27:51
User entered '10 Sep 2020 22:27'	System	11 Sep 2020 03:27:51

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 02:57:21

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 02:57:21

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	11 Sep 2020 03:27:40
User entered 'Day 22'	System	11 Sep 2020 03:27:40

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '11 Sep 2020 12:00'	System	11 Sep 2020 03:27:40

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 03:27:40

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
Data entry locked.	System	11 Sep 2020 03:27:40
User entered 'Day 23'	System	11 Sep 2020 03:27:40

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:23:26

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 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 03:27:40

US3392065

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:23:33
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 03:27:40

US3392065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:02:29
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	16 Sep 2020 14:17:41

US3392065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:02:29
User entered '28 Aug 2020'	Brenda Lawson (b) (4)	16 Sep 2020 14:17:41

US3392065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:02:29
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	16 Sep 2020 14:17:41

US3392065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:02:29
User entered empty.	Brenda Lawson (b) (4)	16 Sep 2020 14:17:41

US3392065

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:02:29
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	16 Sep 2020 14:17:46

US3392065

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'I'	System	16 Sep 2020 14:17:46

US3392065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:29:09
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	16 Sep 2020 14:19:11

US3392065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:29:09
User entered '4 Sep 2020'	Brenda Lawson (b) (4)	16 Sep 2020 14:19:11

US3392065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:29:09
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	16 Sep 2020 14:19:11

US3392065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:29:09
User entered empty.	Brenda Lawson (b) (4)	16 Sep 2020 14:19:11

US3392065

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:29:09
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	16 Sep 2020 14:19:18

US3392065

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'I'	System	16 Sep 2020 14:19:18

US3392065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:09:41
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	16 Sep 2020 14:20:12

US3392065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:09:41
User entered '11 Sep 2020'	Brenda Lawson (b) (4)	16 Sep 2020 14:20:12

US3392065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:09:41
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	16 Sep 2020 14:20:12

US3392065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:09:41
User entered empty.	Brenda Lawson (b) (4)	16 Sep 2020 14:20:12

US3392065

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:09:41
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	16 Sep 2020 14:21:18

US3392065

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'I'	System	16 Sep 2020 14:21:18

US3392065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	16 Sep 2020 14:25:50

US3392065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
Amendment Manager: User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
	System	17 Sep 2020 00:17:56
Amendment Manager: Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	17 Sep 2020 00:17:56
Amendment Manager: Query text changed to "Visit 2 System Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates."		17 Sep 2020 00:17:55
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Sep 2020 14:25:50
User entered '16 Sep 2020'	Brenda Lawson (b) (4)	16 Sep 2020 14:25:50
	(b) (4)	

US3392065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered 'Clinic (Clinic)'	Brenda Lawson (b) (4)	16 Sep 2020 14:25:50

US3392065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered 'VISIT2'	System	16 Sep 2020 14:25:50

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User accepted default value 'Pre-Dose (PREDOSE)'	Brandon Illickal (b) (4)	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered 'Yes (Y)'	(b) (4)	16 Sep 2020 19:22:30
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '16 Sep 2020'	(b) (4)	16 Sep 2020 19:22:30
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '08:46'	(b) (4)	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered '16 Sep 2020 08:46'	System	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '98.2' F	(b) (4)	16 Sep 2020 19:22:30
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered 'Oral (Oral)'	(b) (4)	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered empty.	(b) (4)	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '59'	(b) (4)	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered 'bpm'	System	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '14'	(b) (4)	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered 'breaths/min'	System	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '147'	(b) (4)	16 Sep 2020 19:22:30
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered 'mmHg'	System	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '92'	(b) (4)	16 Sep 2020 19:22:30
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered 'mmHg'	System	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User accepted default value 'Post-Dose (POSTDOSE)'	Brandon Illickal (b) (4)	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered 'Yes (Y)'	(b) (4)	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '16 Sep 2020'	(b) (4)	16 Sep 2020 19:22:30
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '10:48'	(b) (4)	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered '16 Sep 2020 10:48'	System	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '98.6' F	(b) (4)	16 Sep 2020 19:22:30
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered 'Oral (Oral)'	(b) (4)	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered empty.	(b) (4)	16 Sep 2020 19:22:30
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '57'	(b) (4)	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered 'bpm'	System	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '16'	(b) (4)	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered 'breaths/min'	System	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 06:06:33
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	17 Sep 2020 00:17:55
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Brandon Illickal (b) (4)	16 Sep 2020 19:23:01
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 19:22:30
User entered '158'	Brandon Illickal (b) (4)	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered 'mmHg'	System	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '94'	(b) (4)	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered 'mmHg'	System	16 Sep 2020 19:22:30

US3392065

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	16 Sep 2020 14:27:02

US3392065

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '16 Sep 2020'	Brenda Lawson (b) (4)	16 Sep 2020 14:27:02

US3392065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	16 Sep 2020 15:27:50
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	16 Sep 2020 15:27:50
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	16 Sep 2020 15:27:07
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	16 Sep 2020 15:27:07
	(b) (4)	

US3392065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered empty.	Brenda Lawson (b) (4)	16 Sep 2020 15:27:07

US3392065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered empty.	Brenda Lawson (b) (4)	16 Sep 2020 15:27:07

US3392065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 15:27:07

US3392065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Brenda Lawson (b) (4)	16 Sep 2020 15:27:50
User entered empty.	(b) (4)	
	Brenda Lawson (b) (4)	16 Sep 2020 15:27:07
	(b) (4)	

US3392065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '10:17'	Brenda Lawson (b) (4)	16 Sep 2020 15:27:07

US3392065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered '16 Sep 2020 10:17'	System	16 Sep 2020 15:27:50
User entered empty.	System	16 Sep 2020 15:27:07

US3392065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered 'Left Arm (LEFT ARM)'	Brenda Lawson (b) (4)	16 Sep 2020 15:27:07

US3392065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered 'ONCE'	System	16 Sep 2020 15:27:07

US3392065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 15:27:07

US3392065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	16 Sep 2020 14:43:01

US3392065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '16 Sep 2020'	Brenda Lawson (b) (4)	16 Sep 2020 14:43:01

US3392065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '09:07'	Brenda Lawson (b) (4)	16 Sep 2020 14:43:01

US3392065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered '16 Sep 2020 09:07'	System	16 Sep 2020 14:43:01

US3392065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:23:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '16 Sep 2020'	Brenda Lawson (b) (4)	16 Sep 2020 14:43:20

US3392065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Lawson (b) (4) (b) (4)	16 Sep 2020 14:43:20

US3392065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	16 Sep 2020 14:43:20

US3392065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered '09:01'	Brenda Lawson (b) (4)	16 Sep 2020 14:43:20

US3392065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:23:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered '16 Sep 2020 09:01'	System	16 Sep 2020 14:43:20

US3392065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Lawson (b) (4) (b) (4)	16 Sep 2020 14:43:20

US3392065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered 'No (N)'	Brenda Lawson (b) (4)	16 Sep 2020 14:43:20

US3392065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered empty.	Brenda Lawson (b) (4)	16 Sep 2020 14:43:20

US3392065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:23:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered empty.	System	16 Sep 2020 14:43:20

US3392065

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:37:27
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	16 Sep 2020 14:43:33

US3392065

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'I'	System	16 Sep 2020 14:43:33

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:53:04', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '017244fc-51a0-448c-9d06-7da088eb3431'	System	16 Sep 2020 15:53:33
User entered 'Yes (Y)'	System	16 Sep 2020 15:53:33

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:53:14', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '017244fc-51a0-448c-9d06-7da088eb3431'	System	16 Sep 2020 15:53:33
User entered '98.6'	System	16 Sep 2020 15:53:33

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:53:22', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '017244fc-51a0-448c-9d06-7da088eb3431'	System	16 Sep 2020 15:53:33
User entered 'No (N)'	System	16 Sep 2020 15:53:33

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:53:27', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '017244fc-51a0-448c-9d06-7da088eb3431'	System	16 Sep 2020 15:53:33
User entered '16 Sep 2020 10:53'	System	16 Sep 2020 15:53:33

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '16 Sep 2020 10:37'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '16 Sep 2020 13:07'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:14:11', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cf51069c-c8d2-4e23-b181-b306a4e64e2b'	System	17 Sep 2020 02:14:32
User entered 'Yes (Y)'	System	17 Sep 2020 02:14:32

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:14:18', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cf51069c-c8d2-4e23-b181-b306a4e64e2b'	System	17 Sep 2020 02:14:32
User entered '98.4'	System	17 Sep 2020 02:14:32

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:14:23', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cf51069c-c8d2-4e23-b181-b306a4e64e2b'	System	17 Sep 2020 02:14:32
User entered 'No (N)'	System	17 Sep 2020 02:14:32

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:14:27', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cf51069c-c8d2-4e23-b181-b306a4e64e2b'	System	17 Sep 2020 02:14:32
User entered '16 Sep 2020 21:14'	System	17 Sep 2020 02:14:32

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '16 Sep 2020 14:02'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 2'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:51:53', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '25183686-0174-4b1b-8b90-840a423974e6'	System	18 Sep 2020 01:52:20
User entered 'Yes (Y)'	System	18 Sep 2020 01:52:20

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:52:01', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '25183686-0174-4b1b-8b90-840a423974e6'	System	18 Sep 2020 01:52:20
User entered '97.9'	System	18 Sep 2020 01:52:20

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:52:06', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '25183686-0174-4b1b-8b90-840a423974e6'	System	18 Sep 2020 01:52:20
User entered 'No (N)'	System	18 Sep 2020 01:52:20

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:52:10', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '25183686-0174-4b1b-8b90-840a423974e6'	System	18 Sep 2020 01:52:20
User entered '17 Sep 2020 20:52'	System	18 Sep 2020 01:52:20

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 3'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:06:11', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'af9a794e-3c3a-4359-8b09-d936670b538d'	System	19 Sep 2020 03:06:37
User entered 'Yes (Y)'	System	19 Sep 2020 03:06:37

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:06:18', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'af9a794e-3c3a-4359-8b09-d936670b538d'	System	19 Sep 2020 03:06:37
User entered '97.9'	System	19 Sep 2020 03:06:37

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:06:21', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'af9a794e-3c3a-4359-8b09-d936670b538d'	System	19 Sep 2020 03:06:37
User entered 'No (N)'	System	19 Sep 2020 03:06:37

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:06:27', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'af9a794e-3c3a-4359-8b09-d936670b538d'	System	19 Sep 2020 03:06:37
User entered '18 Sep 2020 22:06'	System	19 Sep 2020 03:06:37

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 4'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:15:38', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '29a02747-c2d9-4541-8105-5e6c3065c1d0'	System	20 Sep 2020 05:16:00
User entered 'Yes (Y)'	System	20 Sep 2020 05:16:00

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:15:45', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '29a02747-c2d9-4541-8105-5e6c3065c1d0'	System	20 Sep 2020 05:16:00
User entered '97.4'	System	20 Sep 2020 05:16:00

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:15:49', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '29a02747-c2d9-4541-8105-5e6c3065c1d0'	System	20 Sep 2020 05:16:00
User entered 'No (N)'	System	20 Sep 2020 05:16:00

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:15:52', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '29a02747-c2d9-4541-8105-5e6c3065c1d0'	System	20 Sep 2020 05:16:00
User entered '20 Sep 2020 00:15'	System	20 Sep 2020 05:16:00

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 5'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:23:45', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '46816a02-2f1c-4653-be71-badfbb3c9319'	System	21 Sep 2020 04:24:26
User entered 'Yes (Y)'	System	21 Sep 2020 04:24:26

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:24:00', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '46816a02-2f1c-4653-be71-badfbb3c9319'	System	21 Sep 2020 04:24:26
User entered '97.7'	System	21 Sep 2020 04:24:26

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:24:07', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '46816a02-2f1c-4653-be71-badfbb3c9319'	System	21 Sep 2020 04:24:26
User entered 'Yes (Y)'	System	21 Sep 2020 04:24:26

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
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 13:23:28
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 (ac0ceca948910bc0)', Time: '2020-09-20T23:24:14', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '46816a02-2f1c-4653-be71-badfbb3c9319'	Brandon Illickal (b) (4)	05 Jan 2021 02:11:20
User entered '1'	System	21 Sep 2020 04:24:26
	System	21 Sep 2020 04:24:26
	System	21 Sep 2020 04:24:26

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:24:14', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '46816a02-2f1c-4653-be71-badfbb3c9319'	System	21 Sep 2020 04:24:26
User entered '0'	System	21 Sep 2020 04:24:26

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:24:19', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '46816a02-2f1c-4653-be71-badfbb3c9319'	System	21 Sep 2020 04:24:26
User entered '20 Sep 2020 23:24'	System	21 Sep 2020 04:24:26

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 6'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:36:12', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '99cd9587-3931-4865-ac72-9164b59b722c'	System	22 Sep 2020 06:36:34
User entered 'Yes (Y)'	System	22 Sep 2020 06:36:34

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:36:20', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '99cd9587-3931-4865-ac72-9164b59b722c' User entered '97.3'	System	22 Sep 2020 06:36:34
	System	22 Sep 2020 06:36:34

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:36:27', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '99cd9587-3931-4865-ac72-9164b59b722c'	System	22 Sep 2020 06:36:34
User entered 'No (N)'	System	22 Sep 2020 06:36:34

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:36:32', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '99cd9587-3931-4865-ac72-9164b59b722c'	System	22 Sep 2020 06:36:34
User entered '22 Sep 2020 01:36'	System	22 Sep 2020 06:36:34

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 7'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:17:10', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'a21d9c4b-0837-4c71-b221-47a22d76b606'	System	23 Sep 2020 01:17:27
User entered 'Yes (Y)'	System	23 Sep 2020 01:17:27

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:17:17', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'a21d9c4b-0837-4c71-b221-47a22d76b606'	System	23 Sep 2020 01:17:27
User entered '97.8'	System	23 Sep 2020 01:17:27

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:17:21', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'a21d9c4b-0837-4c71-b221-47a22d76b606'	System	23 Sep 2020 01:17:27
User entered 'No (N)'	System	23 Sep 2020 01:17:27

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:17:25', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'a21d9c4b-0837-4c71-b221-47a22d76b606'	System	23 Sep 2020 01:17:27
User entered '22 Sep 2020 20:17'	System	23 Sep 2020 01:17:27

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:53:35', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '97621928-832c-4d03-aaec-d1241eccb03e'	System	16 Sep 2020 15:54:06
User entered 'None (1)'	System	16 Sep 2020 15:54:06

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:53:43', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '97621928-832c-4d03-aaec-d1241eccb03e'	System	16 Sep 2020 15:54:06
User entered 'No (N)'	System	16 Sep 2020 15:54:06

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:53:49', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '97621928-832c-4d03-aaec-d1241eccb03e'	System	16 Sep 2020 15:54:06
User entered 'No (N)'	System	16 Sep 2020 15:54:06

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:53:58', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '97621928-832c-4d03-aaec-d1241eccb03e'	System	16 Sep 2020 15:54:06
User entered 'None (1)'	System	16 Sep 2020 15:54:06

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:54:01', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '97621928-832c-4d03-aaec-d1241eccb03e'	System	16 Sep 2020 15:54:06
User entered '16 Sep 2020 10:54'	System	16 Sep 2020 15:54:06

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '16 Sep 2020 10:37'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '16 Sep 2020 13:07'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:16:45', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'fb4cbe52-5c0b-4b4f-a571-5a72b84bf21c'	System	17 Sep 2020 02:17:15
User entered 'None (1)'	System	17 Sep 2020 02:17:15

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:16:51', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'fb4cbe52-5c0b-4b4f-a571-5a72b84bf21c'	System	17 Sep 2020 02:17:15
User entered 'No (N)'	System	17 Sep 2020 02:17:15

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:16:55', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'fb4cbe52-5c0b-4b4f-a571-5a72b84bf21c'	System	17 Sep 2020 02:17:15
User entered 'No (N)'	System	17 Sep 2020 02:17:15

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:17:03', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'fb4cbe52-5c0b-4b4f-a571-5a72b84bf21c'	System	17 Sep 2020 02:17:15
User entered 'None (1)'	System	17 Sep 2020 02:17:15

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:17:10', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'fb4cbe52-5c0b-4b4f-a571-5a72b84bf21c'	System	17 Sep 2020 02:17:15
User entered '16 Sep 2020 21:17'	System	17 Sep 2020 02:17:15

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '16 Sep 2020 14:02'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 2'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:52:53', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '224023ae-fe5d-432d-9a01-1332031620f8'	System	18 Sep 2020 01:54:32
User entered 'None (1)'	System	18 Sep 2020 01:54:32

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:53:25', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '224023ae-fe5d-432d-9a01-1332031620f8'	System	18 Sep 2020 01:54:32
User entered 'No (N)'	System	18 Sep 2020 01:54:32

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:54:15', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '224023ae-fe5d-432d-9a01-1332031620f8'	System	18 Sep 2020 01:54:32
User entered 'No (N)'	System	18 Sep 2020 01:54:32

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:54:21', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '224023ae-fe5d-432d-9a01-1332031620f8'	System	18 Sep 2020 01:54:32
User entered 'None (1)'	System	18 Sep 2020 01:54:32

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:54:25', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '224023ae-fe5d-432d-9a01-1332031620f8'	System	18 Sep 2020 01:54:32
User entered '17 Sep 2020 20:54'	System	18 Sep 2020 01:54:32

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 3'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:06:34', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '89f248c4-b556-410b-baaf-7a49a3db7952'	System	19 Sep 2020 03:07:00
User entered 'None (1)'	System	19 Sep 2020 03:07:00

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:06:41', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '89f248c4-b556-410b-baaf-7a49a3db7952'	System	19 Sep 2020 03:07:00
User entered 'No (N)'	System	19 Sep 2020 03:07:00

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:06:44', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '89f248c4-b556-410b-baaf-7a49a3db7952'	System	19 Sep 2020 03:07:00
User entered 'No (N)'	System	19 Sep 2020 03:07:00

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:06:49', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '89f248c4-b556-410b-baaf-7a49a3db7952'	System	19 Sep 2020 03:07:00
User entered 'None (1)'	System	19 Sep 2020 03:07:00

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:06:56', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '89f248c4-b556-410b-baaf-7a49a3db7952'	System	19 Sep 2020 03:07:00
User entered '18 Sep 2020 22:06'	System	19 Sep 2020 03:07:00

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 4'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:15:59', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'c9601801-ef57-4b14-a20b-1976cce89ab1'	System	20 Sep 2020 05:16:18
User entered 'None (1)'	System	20 Sep 2020 05:16:18

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:16:03', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'c9601801-ef57-4b14-a20b-1976cce89ab1'	System	20 Sep 2020 05:16:18
User entered 'No (N)'	System	20 Sep 2020 05:16:18

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:16:07', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'c9601801-ef57-4b14-a20b-1976cce89ab1'	System	20 Sep 2020 05:16:18
User entered 'No (N)'	System	20 Sep 2020 05:16:18

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:16:10', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'c9601801-ef57-4b14-a20b-1976cce89ab1'	System	20 Sep 2020 05:16:18
User entered 'None (1)'	System	20 Sep 2020 05:16:18

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:16:14', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'c9601801-ef57-4b14-a20b-1976cce89ab1'	System	20 Sep 2020 05:16:18
User entered '20 Sep 2020 00:16'	System	20 Sep 2020 05:16:18

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 5'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:24:25', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '31a0614b-5db7-4172-903c-dfc843790841'	System	21 Sep 2020 04:24:44
User entered 'None (1)'	System	21 Sep 2020 04:24:44

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:24:29', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '31a0614b-5db7-4172-903c-dfc843790841'	System	21 Sep 2020 04:24:44
User entered 'No (N)'	System	21 Sep 2020 04:24:44

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:24:32', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '31a0614b-5db7-4172-903c-dfc843790841'	System	21 Sep 2020 04:24:44
User entered 'No (N)'	System	21 Sep 2020 04:24:44

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:24:36', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '31a0614b-5db7-4172-903c-dfc843790841'	System	21 Sep 2020 04:24:44
User entered 'None (1)'	System	21 Sep 2020 04:24:44

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:24:40', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '31a0614b-5db7-4172-903c-dfc843790841'	System	21 Sep 2020 04:24:44
User entered '20 Sep 2020 23:24'	System	21 Sep 2020 04:24:44

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 6'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:37:23', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '0b0585b3-ee9b-47d7-998b-9f352513b78c'	System	22 Sep 2020 06:37:40
User entered 'None (1)'	System	22 Sep 2020 06:37:40

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:37:27', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '0b0585b3-ee9b-47d7-998b-9f352513b78c'	System	22 Sep 2020 06:37:40
User entered 'No (N)'	System	22 Sep 2020 06:37:40

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:37:31', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '0b0585b3-ee9b-47d7-998b-9f352513b78c'	System	22 Sep 2020 06:37:40
User entered 'No (N)'	System	22 Sep 2020 06:37:40

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:37:35', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '0b0585b3-ee9b-47d7-998b-9f352513b78c'	System	22 Sep 2020 06:37:40
User entered 'None (1)'	System	22 Sep 2020 06:37:40

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:37:38', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '0b0585b3-ee9b-47d7-998b-9f352513b78c'	System	22 Sep 2020 06:37:40
User entered '22 Sep 2020 01:37'	System	22 Sep 2020 06:37:40

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 7'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:17:32', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '2f91856e-5d28-4baa-9f36-2f08b4d70146'	System	23 Sep 2020 01:17:52
User entered 'None (1)'	System	23 Sep 2020 01:17:52

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:17:40', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '2f91856e-5d28-4baa-9f36-2f08b4d70146'	System	23 Sep 2020 01:17:52
User entered 'No (N)'	System	23 Sep 2020 01:17:52

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:17:44', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '2f91856e-5d28-4baa-9f36-2f08b4d70146'	System	23 Sep 2020 01:17:52
User entered 'No (N)'	System	23 Sep 2020 01:17:52

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:17:47', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '2f91856e-5d28-4baa-9f36-2f08b4d70146'	System	23 Sep 2020 01:17:52
User entered 'None (1)'	System	23 Sep 2020 01:17:52

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:17:50', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '2f91856e-5d28-4baa-9f36-2f08b4d70146'	System	23 Sep 2020 01:17:52
User entered '22 Sep 2020 20:17'	System	23 Sep 2020 01:17:52

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:54:19', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '69d3b07d-65b9-4c13-9ea5-9feb9abb4090'	System	16 Sep 2020 15:54:57
User entered 'None (0)'	System	16 Sep 2020 15:54:57

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:54:25', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '69d3b07d-65b9-4c13-9ea5-9feb9abb4090'	System	16 Sep 2020 15:54:57
User entered 'None (0)'	System	16 Sep 2020 15:54:57

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:54:28', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '69d3b07d-65b9-4c13-9ea5-9feb9abb4090'	System	16 Sep 2020 15:54:57
User entered 'None (0)'	System	16 Sep 2020 15:54:57

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:54:32', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '69d3b07d-65b9-4c13-9ea5-9feb9abb4090'	System	16 Sep 2020 15:54:57
User entered 'None (0)'	System	16 Sep 2020 15:54:57

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:54:37', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '69d3b07d-65b9-4c13-9ea5-9feb9abb4090' User entered 'None (0)'	System	16 Sep 2020 15:54:57
	System	16 Sep 2020 15:54:57

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:54:41', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '69d3b07d-65b9-4c13-9ea5-9feb9abb4090'	System	16 Sep 2020 15:54:57
User entered 'None (0)'	System	16 Sep 2020 15:54:57

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:54:45', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '69d3b07d-65b9-4c13-9ea5-9feb9abb4090'	System	16 Sep 2020 15:54:57
User entered 'No (N)'	System	16 Sep 2020 15:54:57

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T10:54:51', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '69d3b07d-65b9-4c13-9ea5-9feb9abb4090'	System	16 Sep 2020 15:54:57
User entered '16 Sep 2020 10:54'	System	16 Sep 2020 15:54:57

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '16 Sep 2020 10:37'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '16 Sep 2020 13:07'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:17:17', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '5d281894-f941-4621-af47-f0706d279811'	System	17 Sep 2020 02:17:58
User entered 'None (0)'	System	17 Sep 2020 02:17:58

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:17:23', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '5d281894-f941-4621-af47-f0706d279811'	System	17 Sep 2020 02:17:58
User entered 'Some interference with activity (2)'	System	17 Sep 2020 02:17:58

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:17:27', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '5d281894-f941-4621-af47-f0706d279811'	System	17 Sep 2020 02:17:58
User entered 'None (0)'	System	17 Sep 2020 02:17:58

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:17:31', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '5d281894-f941-4621-af47-f0706d279811'	System	17 Sep 2020 02:17:58
User entered 'None (0)'	System	17 Sep 2020 02:17:58

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:17:36', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '5d281894-f941-4621-af47-f0706d279811'	System	17 Sep 2020 02:17:58
User entered 'None (0)'	System	17 Sep 2020 02:17:58

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:17:40', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '5d281894-f941-4621-af47-f0706d279811'	System	17 Sep 2020 02:17:58
User entered 'None (0)'	System	17 Sep 2020 02:17:58

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:17:45', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '5d281894-f941-4621-af47-f0706d279811'	System	17 Sep 2020 02:17:58
User entered 'No (N)'	System	17 Sep 2020 02:17:58

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-16T21:17:54', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '5d281894-f941-4621-af47-f0706d279811'	System	17 Sep 2020 02:17:58
User entered '16 Sep 2020 21:17'	System	17 Sep 2020 02:17:58

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '16 Sep 2020 14:02'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 2'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:54:50', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '577a11c7-f3ae-4dd6-b746-0fa184e8c41d'	System	18 Sep 2020 01:55:27
User entered 'No interference with activity (1)'	System	18 Sep 2020 01:55:27

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:54:57', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '577a11c7-f3ae-4dd6-b746-0fa184e8c41d'	System	18 Sep 2020 01:55:27
User entered 'None (0)'	System	18 Sep 2020 01:55:27

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:55:01', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '577a11c7-f3ae-4dd6-b746-0fa184e8c41d'	System	18 Sep 2020 01:55:27
User entered 'None (0)'	System	18 Sep 2020 01:55:27

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:55:05', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '577a11c7-f3ae-4dd6-b746-0fa184e8c41d' User entered 'None (0)'	System	18 Sep 2020 01:55:27
	System	18 Sep 2020 01:55:27

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:55:09', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '577a11c7-f3ae-4dd6-b746-0fa184e8c41d'	System	18 Sep 2020 01:55:27
User entered 'None (0)'	System	18 Sep 2020 01:55:27

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:55:12', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '577a11c7-f3ae-4dd6-b746-0fa184e8c41d'	System	18 Sep 2020 01:55:27
User entered 'None (0)'	System	18 Sep 2020 01:55:27

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:55:16', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '577a11c7-f3ae-4dd6-b746-0fa184e8c41d'	System	18 Sep 2020 01:55:27
User entered 'No (N)'	System	18 Sep 2020 01:55:27

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-17T20:55:22', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '577a11c7-f3ae-4dd6-b746-0fa184e8c41d'	System	18 Sep 2020 01:55:27
User entered '17 Sep 2020 20:55'	System	18 Sep 2020 01:55:27

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 3'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:07:01', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e3069564-017b-4daf-9d93-fb005f6c8c19'	System	19 Sep 2020 03:07:40
User entered 'None (0)'	System	19 Sep 2020 03:07:40

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:07:08', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e3069564-017b-4daf-9d93-fb005f6c8c19'	System	19 Sep 2020 03:07:40
User entered 'None (0)'	System	19 Sep 2020 03:07:40

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:07:13', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e3069564-017b-4daf-9d93-fb005f6c8c19'	System	19 Sep 2020 03:07:40
User entered 'None (0)'	System	19 Sep 2020 03:07:40

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:07:17', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e3069564-017b-4daf-9d93-fb005f6c8c19'	System	19 Sep 2020 03:07:40
User entered 'None (0)'	System	19 Sep 2020 03:07:40

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:07:22', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e3069564-017b-4daf-9d93-fb005f6c8c19'	System	19 Sep 2020 03:07:40
User entered 'None (0)'	System	19 Sep 2020 03:07:40

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:07:25', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e3069564-017b-4daf-9d93-fb005f6c8c19'	System	19 Sep 2020 03:07:40
User entered 'None (0)'	System	19 Sep 2020 03:07:40

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:07:29', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e3069564-017b-4daf-9d93-fb005f6c8c19'	System	19 Sep 2020 03:07:40
User entered 'No (N)'	System	19 Sep 2020 03:07:40

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-18T22:07:32', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e3069564-017b-4daf-9d93-fb005f6c8c19'	System	19 Sep 2020 03:07:40
User entered '18 Sep 2020 22:07'	System	19 Sep 2020 03:07:40

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 4'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:16:21', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '44fe8bd2-04d5-49f9-8977-501441c30d5b'	System	20 Sep 2020 05:16:56
User entered 'None (0)'	System	20 Sep 2020 05:16:56

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:16:27', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '44fe8bd2-04d5-49f9-8977-501441c30d5b'	System	20 Sep 2020 05:16:56
User entered 'None (0)'	System	20 Sep 2020 05:16:56

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:16:31', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '44fe8bd2-04d5-49f9-8977-501441c30d5b'	System	20 Sep 2020 05:16:56
User entered 'None (0)'	System	20 Sep 2020 05:16:56

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:16:35', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '44fe8bd2-04d5-49f9-8977-501441c30d5b'	System	20 Sep 2020 05:16:56
User entered 'None (0)'	System	20 Sep 2020 05:16:56

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:16:39', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '44fe8bd2-04d5-49f9-8977-501441c30d5b'	System	20 Sep 2020 05:16:56
User entered 'None (0)'	System	20 Sep 2020 05:16:56

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:16:43', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '44fe8bd2-04d5-49f9-8977-501441c30d5b'	System	20 Sep 2020 05:16:56
User entered 'None (0)'	System	20 Sep 2020 05:16:56

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:16:48', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '44fe8bd2-04d5-49f9-8977-501441c30d5b'	System	20 Sep 2020 05:16:56
User entered 'No (N)'	System	20 Sep 2020 05:16:56

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T00:16:51', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '44fe8bd2-04d5-49f9-8977-501441c30d5b'	System	20 Sep 2020 05:16:56
User entered '20 Sep 2020 00:16'	System	20 Sep 2020 05:16:56

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 5'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:25:01', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e78eba6e-a9c7-4521-9268-5d1a8e912feb'	System	21 Sep 2020 04:25:48
User entered 'No interference with activity (1)'	System	21 Sep 2020 04:25:48

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:25:05', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e78eba6e-a9c7-4521-9268-5d1a8e912feb'	System	21 Sep 2020 04:25:48
User entered 'None (0)'	System	21 Sep 2020 04:25:48

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:25:09', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e78eba6e-a9c7-4521-9268-5d1a8e912feb'	System	21 Sep 2020 04:25:48
User entered 'None (0)'	System	21 Sep 2020 04:25:48

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:25:14', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e78eba6e-a9c7-4521-9268-5d1a8e912feb'	System	21 Sep 2020 04:25:48
User entered 'None (0)'	System	21 Sep 2020 04:25:48

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:25:20', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e78eba6e-a9c7-4521-9268-5d1a8e912feb'	System	21 Sep 2020 04:25:48
User entered 'None (0)'	System	21 Sep 2020 04:25:48

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:25:29', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e78eba6e-a9c7-4521-9268-5d1a8e912feb'	System	21 Sep 2020 04:25:48
User entered 'None (0)'	System	21 Sep 2020 04:25:48

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:25:38', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e78eba6e-a9c7-4521-9268-5d1a8e912feb'	System	21 Sep 2020 04:25:48
User entered 'No (N)'	System	21 Sep 2020 04:25:48

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-20T23:25:44', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'e78eba6e-a9c7-4521-9268-5d1a8e912feb'	System	21 Sep 2020 04:25:48
User entered '20 Sep 2020 23:25'	System	21 Sep 2020 04:25:48

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 6'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:37:48', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '815ff926-eac4-448f-9be6-82a2fcaba662'	System	22 Sep 2020 06:38:19
User entered 'No interference with activity (1)'	System	22 Sep 2020 06:38:19

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:37:53', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '815ff926-eac4-448f-9be6-82a2fcaba662'	System	22 Sep 2020 06:38:19
User entered 'None (0)'	System	22 Sep 2020 06:38:19

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:37:56', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '815ff926-eac4-448f-9be6-82a2fcaba662'	System	22 Sep 2020 06:38:19
User entered 'None (0)'	System	22 Sep 2020 06:38:19

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:37:59', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '815ff926-eac4-448f-9be6-82a2fcaba662'	System	22 Sep 2020 06:38:19
User entered 'None (0)'	System	22 Sep 2020 06:38:19

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:38:02', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '815ff926-eac4-448f-9be6-82a2fcaba662'	System	22 Sep 2020 06:38:19
User entered 'None (0)'	System	22 Sep 2020 06:38:19

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:38:06', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '815ff926-eac4-448f-9be6-82a2fcaba662'	System	22 Sep 2020 06:38:19
User entered 'None (0)'	System	22 Sep 2020 06:38:19

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:38:12', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '815ff926-eac4-448f-9be6-82a2fcaba662'	System	22 Sep 2020 06:38:19
User entered 'No (N)'	System	22 Sep 2020 06:38:19

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T01:38:15', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '815ff926-eac4-448f-9be6-82a2fcaba662'	System	22 Sep 2020 06:38:19
User entered '22 Sep 2020 01:38'	System	22 Sep 2020 06:38:19

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	16 Sep 2020 15:27:50
User entered 'Day 7'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:18:01', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd1ac36db-149a-4844-8dcd-2b8c6d7f2f87'	System	23 Sep 2020 01:18:37
User entered 'None (0)'	System	23 Sep 2020 01:18:37

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:18:05', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd1ac36db-149a-4844-8dcd-2b8c6d7f2f87'	System	23 Sep 2020 01:18:37
User entered 'None (0)'	System	23 Sep 2020 01:18:37

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:18:08', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd1ac36db-149a-4844-8dcd-2b8c6d7f2f87'	System	23 Sep 2020 01:18:37
User entered 'None (0)'	System	23 Sep 2020 01:18:37

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:18:12', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd1ac36db-149a-4844-8dcd-2b8c6d7f2f87'	System	23 Sep 2020 01:18:37
User entered 'None (0)'	System	23 Sep 2020 01:18:37

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:18:17', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd1ac36db-149a-4844-8dcd-2b8c6d7f2f87'	System	23 Sep 2020 01:18:37
User entered 'None (0)'	System	23 Sep 2020 01:18:37

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:18:21', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd1ac36db-149a-4844-8dcd-2b8c6d7f2f87'	System	23 Sep 2020 01:18:37
User entered 'None (0)'	System	23 Sep 2020 01:18:37

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:18:25', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd1ac36db-149a-4844-8dcd-2b8c6d7f2f87'	System	23 Sep 2020 01:18:37
User entered 'No (N)'	System	23 Sep 2020 01:18:37

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-09-22T20:18:28', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd1ac36db-149a-4844-8dcd-2b8c6d7f2f87'	System	23 Sep 2020 01:18:37
User entered '22 Sep 2020 20:18'	System	23 Sep 2020 01:18:37

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:27:50

US3392065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:23:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:27:50

US3392065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:53:15
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	23 Sep 2020 18:55:57

US3392065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:53:15
User entered '23 Sep 2020'	Brenda Lawson (b) (4)	23 Sep 2020 18:55:57

US3392065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:53:15
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	23 Sep 2020 18:55:57

US3392065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:53:15
User entered empty.	Brenda Lawson (b) (4)	23 Sep 2020 18:55:57

US3392065

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:53:15
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	23 Sep 2020 18:56:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Lawson (b) (4)	23 Sep 2020 18:56:04
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Sep 2020 18:55:59
	Brenda Lawson (b) (4)	23 Sep 2020 18:55:59
	(b) (4)	

US3392065

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'I'	System	23 Sep 2020 18:56:04
User entered empty.	System	23 Sep 2020 18:55:59

US3392065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:36:52
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	30 Sep 2020 21:04:19

US3392065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:36:52
User entered '30 Sep 2020'	Brenda Lawson (b) (4)	30 Sep 2020 21:04:19

US3392065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:36:52
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	30 Sep 2020 21:04:19

US3392065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:36:52
User entered empty.	Brenda Lawson (b) (4)	30 Sep 2020 21:04:19

US3392065

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:36:52
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	30 Sep 2020 21:04:24

US3392065

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'I'	System	30 Sep 2020 21:04:24

US3392065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:19:15
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	07 Oct 2020 14:54:45

US3392065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:19:15
User entered '7 Oct 2020'	Brenda Lawson (b) (4)	07 Oct 2020 14:54:45

US3392065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:19:15
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	07 Oct 2020 14:54:45

US3392065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:19:15
User entered empty.	Brenda Lawson (b) (4)	07 Oct 2020 14:54:45

US3392065

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:19:15
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	07 Oct 2020 14:54:50

US3392065

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'I'	System	07 Oct 2020 14:54:50

US3392065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered 'Yes (Y)'	(b) (4)	12 Oct 2020 16:09:53

US3392065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered '12 Oct 2020'	(b) (4)	12 Oct 2020 16:09:53
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered 'Clinic (Clinic)'	(b) (4)	12 Oct 2020 16:09:53
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered 'VISIT3'	System	12 Oct 2020 16:09:53

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered 'No (N)'	(b) (4)	12 Oct 2020 16:10:00
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered empty.	(b) (4)	12 Oct 2020 16:10:00
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered empty.	(b) (4)	12 Oct 2020 16:10:00
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered empty.	System	12 Oct 2020 16:10:00

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered empty.	(b) (4)	12 Oct 2020 16:10:00
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered empty.	(b) (4)	12 Oct 2020 16:10:00
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered empty.	(b) (4)	12 Oct 2020 16:10:00
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered empty.	(b) (4)	12 Oct 2020 16:10:00
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered empty.	System	12 Oct 2020 16:10:00

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered empty.	(b) (4)	12 Oct 2020 16:10:00
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered empty.	System	12 Oct 2020 16:10:00

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered empty.	(b) (4)	12 Oct 2020 16:10:00
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered empty.	System	12 Oct 2020 16:10:00

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered empty.	(b) (4)	12 Oct 2020 16:10:00
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered empty.	System	12 Oct 2020 16:10:00

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42

US3392065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42

US3392065

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered 'No (N)'	(b) (4)	12 Oct 2020 16:10:07
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered empty.	(b) (4)	12 Oct 2020 16:10:07
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered 'Yes (Y)'	(b) (4)	12 Oct 2020 16:10:16
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered '12 Oct 2020'	(b) (4)	12 Oct 2020 16:10:16
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered '10:03'	(b) (4)	12 Oct 2020 16:10:16
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered '12 Oct 2020 10:03'	System	12 Oct 2020 16:10:16

US3392065

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:19:30
User entered 'Yes (Y)'	(b) (4)	12 Oct 2020 16:10:22
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:42
User entered 'I'	System	12 Oct 2020 16:10:22

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 64'	System	21 Aug 2020 16:13:27

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-10-21T17:16:06', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd9b2e273-0bea-475a-8adc-9e72fa53ae79'	System	21 Oct 2020 22:16:27
User entered 'No (N)'	System	21 Oct 2020 22:16:27

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-10-21T17:16:14', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd9b2e273-0bea-475a-8adc-9e72fa53ae79'	System	21 Oct 2020 22:16:27
User entered 'No (N)'	System	21 Oct 2020 22:16:27

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-10-21T17:16:22', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'd9b2e273-0bea-475a-8adc-9e72fa53ae79'	System	21 Oct 2020 22:16:27
User entered '21 Oct 2020 17:16:22'	System	21 Oct 2020 22:16:27

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 16:13:27

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 71'	System	21 Aug 2020 16:13:27

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-10-30T16:40:05', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ff15c6d8-d607-485d-8162-c5b067039f8d'	System	30 Oct 2020 21:40:22
User entered 'No (N)'	System	30 Oct 2020 21:40:22

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-10-30T16:40:10', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ff15c6d8-d607-485d-8162-c5b067039f8d'	System	30 Oct 2020 21:40:22
User entered 'No (N)'	System	30 Oct 2020 21:40:22

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-10-30T16:40:19', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'ff15c6d8-d607-485d-8162-c5b067039f8d'	System	30 Oct 2020 21:40:22
User entered '30 Oct 2020 16:40:19'	System	30 Oct 2020 21:40:22

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 16:13:27

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 78'	System	21 Aug 2020 16:13:27

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-11-04T08:24:02', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '509da5b0-c63d-4f39-9f5b-1aab319790d6'	System	04 Nov 2020 14:24:19
User entered 'No (N)'	System	04 Nov 2020 14:24:19

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-11-04T08:24:08', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '509da5b0-c63d-4f39-9f5b-1aab319790d6'	System	04 Nov 2020 14:24:19
User entered 'No (N)'	System	04 Nov 2020 14:24:19

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-11-04T08:24:15', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '509da5b0-c63d-4f39-9f5b-1aab319790d6'	System	04 Nov 2020 14:24:19
User entered '04 Nov 2020 08:24:15'	System	04 Nov 2020 14:24:19

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 16:13:27

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered 'Day 92'	System	21 Aug 2020 16:13:27

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-11-18T11:39:22', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '69a243f4-adf4-4d4f-84fa-7efb4c14647d'	System	18 Nov 2020 17:39:40
User entered 'No (N)'	System	18 Nov 2020 17:39:40

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-11-18T11:38:31', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '69a243f4-adf4-4d4f-84fa-7efb4c14647d'	System	18 Nov 2020 17:39:40
User entered 'No (N)'	System	18 Nov 2020 17:39:40

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-11-18T11:39:34', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '69a243f4-adf4-4d4f-84fa-7efb4c14647d'	System	18 Nov 2020 17:39:40
User entered '18 Nov 2020 11:39:34'	System	18 Nov 2020 17:39:40

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 16:13:27

US3392065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:24:24
Data entry locked.	System	21 Aug 2020 16:13:27
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 16:13:27

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2020-11-23T13:32:43', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cf00724a-2c70-45d8-86be-3894de75fe51'	System	23 Nov 2020 19:32:57
User entered 'No (N)'	System	23 Nov 2020 19:32:57

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2020-11-23T13:32:48', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cf00724a-2c70-45d8-86be-3894de75fe51'	System	23 Nov 2020 19:32:57
User entered 'No (N)'	System	23 Nov 2020 19:32:57

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-11-23T13:32:54', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cf00724a-2c70-45d8-86be-3894de75fe51'	System	23 Nov 2020 19:32:57
User entered '23 Nov 2020 13:32:54'	System	23 Nov 2020 19:32:57

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2020-11-29T06:41:18', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '446cb9ef-41ea-48b2-a9d9-38fbcefa14e4'	System	29 Nov 2020 12:41:41
User entered 'No (N)'	System	29 Nov 2020 12:41:41

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2020-11-29T06:41:25', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '446cb9ef-41ea-48b2-a9d9-38fbcefa14e4'	System	29 Nov 2020 12:41:41
User entered 'No (N)'	System	29 Nov 2020 12:41:41

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-11-29T06:41:37', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '446cb9ef-41ea-48b2-a9d9-38fbcefa14e4' User entered '29 Nov 2020 06:41:37'	System	29 Nov 2020 12:41:41
	System	29 Nov 2020 12:41:41

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2020-12-09T15:11:11', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '8c787034-4617-40e4-a99e-82b405217fb8'	System	09 Dec 2020 21:11:22
User entered 'No (N)'	System	09 Dec 2020 21:11:22

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2020-12-09T15:11:15', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '8c787034-4617-40e4-a99e-82b405217fb8'	System	09 Dec 2020 21:11:22
User entered 'No (N)'	System	09 Dec 2020 21:11:22

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-12-09T15:11:19', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '8c787034-4617-40e4-a99e-82b405217fb8'	System	09 Dec 2020 21:11:22
User entered '09 Dec 2020 15:11:19'	System	09 Dec 2020 21:11:22

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2020-12-15T04:40:30', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '249ce7b8-a2d4-4513-9001-381d5b4e8188'	System	15 Dec 2020 10:40:45
User entered 'No (N)'	System	15 Dec 2020 10:40:45

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2020-12-15T04:40:36', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '249ce7b8-a2d4-4513-9001-381d5b4e8188'	System	15 Dec 2020 10:40:45
User entered 'No (N)'	System	15 Dec 2020 10:40:45

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-12-15T04:40:42', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '249ce7b8-a2d4-4513-9001-381d5b4e8188' User entered '15 Dec 2020 04:40:42'	System	15 Dec 2020 10:40:45
	System	15 Dec 2020 10:40:45

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2020-12-22T01:40:51', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '6fdb2902-6207-4f9d-8593-124f9f937710'	System	22 Dec 2020 07:41:12
User entered 'No (N)'	System	22 Dec 2020 07:41:12

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2020-12-22T01:40:58', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '6fdb2902-6207-4f9d-8593-124f9f937710'	System	22 Dec 2020 07:41:12
User entered 'No (N)'	System	22 Dec 2020 07:41:12

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-12-22T01:41:06', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '6fdb2902-6207-4f9d-8593-124f9f937710'	System	22 Dec 2020 07:41:12
User entered '22 Dec 2020 01:41:06'	System	22 Dec 2020 07:41:12

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2020-12-31T06:16:04', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cc6c0c8c-edb0-464c-92e2-fca9d4c5c8b8'	System	31 Dec 2020 12:16:28
User entered 'No (N)'	System	31 Dec 2020 12:16:28

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2020-12-31T06:16:15', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cc6c0c8c-edb0-464c-92e2-fca9d4c5c8b8'	System	31 Dec 2020 12:16:28
User entered 'No (N)'	System	31 Dec 2020 12:16:28

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2020-12-31T06:16:24', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'cc6c0c8c-edb0-464c-92e2-fca9d4c5c8b8'	System	31 Dec 2020 12:16:28
User entered '31 Dec 2020 06:16:24'	System	31 Dec 2020 12:16:28

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-01-07T02:59:51', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'b8cf9c38-2657-4ce7-accb-a87721e9f696'	System	07 Jan 2021 09:00:17
User entered 'No (N)'	System	07 Jan 2021 09:00:17

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2021-01-07T03:00:02', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'b8cf9c38-2657-4ce7-accb-a87721e9f696'	System	07 Jan 2021 09:00:17
User entered 'No (N)'	System	07 Jan 2021 09:00:17

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2021-01-07T03:00:14', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'b8cf9c38-2657-4ce7-accb-a87721e9f696'	System	07 Jan 2021 09:00:17
User entered '07 Jan 2021 03:00:14'	System	07 Jan 2021 09:00:17

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-01-11T10:04:30', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '19dea98d-32b6-4de6-9c87-3f6bf358aa3b'	System	11 Jan 2021 16:04:49
User entered 'No (N)'	System	11 Jan 2021 16:04:49

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2021-01-11T10:04:37', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '19dea98d-32b6-4de6-9c87-3f6bf358aa3b'	System	11 Jan 2021 16:04:49
User entered 'No (N)'	System	11 Jan 2021 16:04:49

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2021-01-11T10:04:44', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '19dea98d-32b6-4de6-9c87-3f6bf358aa3b' User entered '11 Jan 2021 10:04:44'	System	11 Jan 2021 16:04:49
	System	11 Jan 2021 16:04:49

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-01-21T09:31:13', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4d2a6ea8-933d-4133-a7e4-466d7b3a9a8e'	System	21 Jan 2021 15:31:28
User entered 'No (N)'	System	21 Jan 2021 15:31:28

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2021-01-21T09:31:18', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4d2a6ea8-933d-4133-a7e4-466d7b3a9a8e'	System	21 Jan 2021 15:31:28
User entered 'No (N)'	System	21 Jan 2021 15:31:28

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2021-01-21T09:31:22', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '4d2a6ea8-933d-4133-a7e4-466d7b3a9a8e' User entered '21 Jan 2021 09:31:22'	System	21 Jan 2021 15:31:28
	System	21 Jan 2021 15:31:28

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-01-31T05:08:54', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '984aea0c-66f0-4f68-99c9-65ec6e03190f'	System	31 Jan 2021 11:09:10
User entered 'No (N)'	System	31 Jan 2021 11:09:10

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2021-01-31T05:09:00', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '984aea0c-66f0-4f68-99c9-65ec6e03190f'	System	31 Jan 2021 11:09:10
User entered 'No (N)'	System	31 Jan 2021 11:09:10

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2021-01-31T05:09:05', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '984aea0c-66f0-4f68-99c9-65ec6e03190f' User entered '31 Jan 2021 05:09:05'	System	31 Jan 2021 11:09:10
	System	31 Jan 2021 11:09:10

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-02-07T02:52:20', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '43a89b4a-4a12-4b73-95e4-3dd4c1bf6532'	System	07 Feb 2021 08:53:06
User entered 'Yes (Y)'	System	07 Feb 2021 08:53:06

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2021-02-07T02:52:26', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '43a89b4a-4a12-4b73-95e4-3dd4c1bf6532'	System	07 Feb 2021 08:53:06
User entered 'No (N)'	System	07 Feb 2021 08:53:06

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-02-07T02:52:35', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '43a89b4a-4a12-4b73-95e4-3dd4c1bf6532'	System	07 Feb 2021 08:53:06
User entered 'No (N)'	System	07 Feb 2021 08:53:06

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-02-07T02:52:43', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '43a89b4a-4a12-4b73-95e4-3dd4c1bf6532'	System	07 Feb 2021 08:53:06
User entered 'No (N)'	System	07 Feb 2021 08:53:06

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2021-02-07T02:53:01', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '43a89b4a-4a12-4b73-95e4-3dd4c1bf6532'	System	07 Feb 2021 08:53:06
User entered '07 Feb 2021 02:53:01'	System	07 Feb 2021 08:53:06

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-02-14T02:23:48', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '95c547d6-38a9-4f08-aeaa-91ada6e592de'	System	14 Feb 2021 08:24:04
User entered 'No (N)'	System	14 Feb 2021 08:24:04

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2021-02-14T02:23:54', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '95c547d6-38a9-4f08-aeaa-91ada6e592de'	System	14 Feb 2021 08:24:04
User entered 'No (N)'	System	14 Feb 2021 08:24:04

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2021-02-14T02:24:01', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '95c547d6-38a9-4f08-aeaa-91ada6e592de'	System	14 Feb 2021 08:24:04
User entered '14 Feb 2021 02:24:01'	System	14 Feb 2021 08:24:04

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-02-21T06:20:58', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '37bd6728-9fac-4560-afce-2a060b018958'	System	21 Feb 2021 12:21:12
User entered 'No (N)'	System	21 Feb 2021 12:21:12

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2021-02-21T06:21:03', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '37bd6728-9fac-4560-afce-2a060b018958'	System	21 Feb 2021 12:21:12
User entered 'No (N)'	System	21 Feb 2021 12:21:12

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2021-02-21T06:21:10', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '37bd6728-9fac-4560-afce-2a060b018958'	System	21 Feb 2021 12:21:12
User entered '21 Feb 2021 06:21:10'	System	21 Feb 2021 12:21:12

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-02-28T14:25:03', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '45a71712-6906-4416-8623-13a7c8e8c23d'	System	28 Feb 2021 20:25:21
User entered 'No (N)'	System	28 Feb 2021 20:25:21

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2021-02-28T14:25:11', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '45a71712-6906-4416-8623-13a7c8e8c23d'	System	28 Feb 2021 20:25:21
User entered 'No (N)'	System	28 Feb 2021 20:25:21

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2021-02-28T14:25:17', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '45a71712-6906-4416-8623-13a7c8e8c23d'	System	28 Feb 2021 20:25:21
User entered '28 Feb 2021 14:25:17'	System	28 Feb 2021 20:25:21

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-03-25T13:23:13', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f8ee89aa-c569-4e88-a78d-a235e5685431'	System	25 Mar 2021 18:24:25
User entered 'Yes (Y)'	System	25 Mar 2021 18:24:25

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2021-03-25T13:23:18', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f8ee89aa-c569-4e88-a78d-a235e5685431'	System	25 Mar 2021 18:24:25
User entered 'No (N)'	System	25 Mar 2021 18:24:25

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-03-25T13:23:23', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f8ee89aa-c569-4e88-a78d-a235e5685431'	System	25 Mar 2021 18:24:25
User entered 'No (N)'	System	25 Mar 2021 18:24:25

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-03-25T13:23:31', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f8ee89aa-c569-4e88-a78d-a235e5685431'	System	25 Mar 2021 18:24:25
User entered 'Yes (Y)'	System	25 Mar 2021 18:24:25

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Please 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 (ac0ceca948910bc0)', Time: '2021-03-25T13:23:43', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f8ee89aa-c569-4e88-a78d-a235e5685431'	System	25 Mar 2021 18:24:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Mar 2021 18:24:25

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2021-03-25T13:24:12', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: 'f8ee89aa-c569-4e88-a78d-a235e5685431' User entered '25 Mar 2021 13:24:12'	System	25 Mar 2021 18:24:25

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-04-01T09:28:36', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '8e9684dc-8d54-4050-ad0b-2d4dceb88089'	System	01 Apr 2021 14:28:51
User entered 'No (N)'	System	01 Apr 2021 14:28:51

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2021-04-01T09:28:41', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '8e9684dc-8d54-4050-ad0b-2d4dceb88089'	System	01 Apr 2021 14:28:51
User entered 'No (N)'	System	01 Apr 2021 14:28:51

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2021-04-01T09:28:47', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '8e9684dc-8d54-4050-ad0b-2d4dceb88089'	System	01 Apr 2021 14:28:51
User entered '01 Apr 2021 09:28:47'	System	01 Apr 2021 14:28:51

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[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 (ac0ceca948910bc0)', Time: '2021-04-04T03:17:50', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '8b8a72f1-c864-4c65-851b-230cee86e244'	System	04 Apr 2021 08:18:10
User entered 'No (N)'	System	04 Apr 2021 08:18:10

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

Have you been exposed to someone with 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 (ac0ceca948910bc0)', Time: '2021-04-04T03:17:58', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '8b8a72f1-c864-4c65-851b-230cee86e244'	System	04 Apr 2021 08:18:10
User entered 'No (N)'	System	04 Apr 2021 08:18:10

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2021-04-04T03:18:07', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '8b8a72f1-c864-4c65-851b-230cee86e244'	System	04 Apr 2021 08:18:10
User entered '04 Apr 2021 03:18:07'	System	04 Apr 2021 08:18:10

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:31:40

US3392065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:23:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:31:40
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:31:40

US3392065

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:23:26

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 07:40:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2021-02-27T13:37:44', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3403ad5a-5eef-4ef4-9088-acd2fbd82197'	System	27 Feb 2021 19:38:01
User entered 'No (N)'	System	27 Feb 2021 19:38:01

US3392065

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:23:26

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:40:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ac0ceca948910bc0)', Time: '2021-02-27T13:37:57', User OID: 'PatientReportedOutcome (US3392065)', ODM File OID: '3403ad5a-5eef-4ef4-9088-acd2fbd82197'	System	27 Feb 2021 19:38:01
User entered '27 Feb 2021 13:37:57'	System	27 Feb 2021 19:38:01

US3392065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:53:12
User entered 'Yes (Y)'	(b) (4)	12 Nov 2020 16:51:34

US3392065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:53:12
User entered '9 Nov 2020'	(b) (4)	12 Nov 2020 16:51:34

US3392065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:53:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	12 Nov 2020 16:51:34

US3392065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:53:12
User entered empty.	(b) (4)	12 Nov 2020 16:51:34
	Brandon Illickal (b) (4)	

US3392065

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:53:12
User entered 'Yes (Y)'	(b) (4)	12 Nov 2020 16:51:24

US3392065

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:25:41
User entered 'I'	System	12 Nov 2020 16:51:24

US3392065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:02:30
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	06 Jan 2021 19:47:46

US3392065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:02:30
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '01 Dec 2020'	Brenda Lawson (b) (4)	06 Jan 2021 19:47:46

US3392065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:02:30
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	06 Jan 2021 19:47:46

US3392065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:02:30
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	Brenda Lawson (b) (4)	06 Jan 2021 19:47:46

US3392065

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:02:30
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	06 Jan 2021 19:48:02

US3392065

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:02:30
User entered 'I'	System	06 Jan 2021 19:48:02

US3392065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:13:22

US3392065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:13:22

US3392065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:13:22

US3392065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:13:22

US3392065

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:13:27

US3392065

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:13
User entered 'I'	System	11 Jan 2021 21:13:27

US3392065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:36:38
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:13:22

US3392065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:36:38
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:13:22

US3392065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:36:38
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:13:22

US3392065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:36:38
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:13:22

US3392065

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:36:38
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:13:27

US3392065

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:36:38
User entered 'I'	System	03 Mar 2021 21:13:27

US3392065

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:13:44

US3392065

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:13:44

US3392065

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[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 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:13:44

US3392065

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User entered 'VISIT4'	System	03 Mar 2021 21:13:44

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'No (N)'	(b) (4)	31 Mar 2021 22:10:47

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4)	31 Mar 2021 22:10:47
	Brandon Illickal (b) (4)	

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4)	31 Mar 2021 22:10:47

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User entered empty.	System	31 Mar 2021 22:10:47

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4)	31 Mar 2021 22:10:47

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4)	31 Mar 2021 22:10:47

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4)	31 Mar 2021 22:10:47

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4)	31 Mar 2021 22:10:47

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User entered empty.	System	31 Mar 2021 22:10:47

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4)	31 Mar 2021 22:10:47

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User entered empty.	System	31 Mar 2021 22:10:47

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4)	31 Mar 2021 22:10:47

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User entered empty.	System	31 Mar 2021 22:10:47

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4)	31 Mar 2021 22:10:47

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User entered empty.	System	31 Mar 2021 22:10:47

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36

US3392065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36

US3392065

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:13:49

US3392065

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:13:49

US3392065

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:14:01

US3392065

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:14:01

US3392065

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '10:25'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:14:01

US3392065

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User entered '3 Mar 2021 10:25'	System	03 Mar 2021 21:14:01

US3392065

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:14:11

US3392065

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:36
User entered 'I'	System	03 Mar 2021 21:14:11

US3392065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:51:52

US3392065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:51:52

US3392065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:51:52

US3392065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:51:52

US3392065

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:51:55

US3392065

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 17:51:55

US3392065

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

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	11 Jan 2021 16:58:59

US3392065

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

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '11 Jan 2021'	Brenda Lawson (b) (4)	11 Jan 2021 16:58:59

US3392065

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

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Clinic (Clinic)'	Brenda Lawson (b) (4)	11 Jan 2021 16:58:59

US3392065

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

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 16:58:59

US3392065

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

Form: Unblinding

Generated On: 09 Jun 2021 17:23:26

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '11 Jan 2021'	Brenda Lawson (b) (4)	11 Jan 2021 17:01:12

US3392065

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

Form: Unblinding

Generated On: 09 Jun 2021 17:23:26

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 19:50:27
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:13:06

US3392065

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

Form: Unblinding

Generated On: 09 Jun 2021 17:23:26

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	11 Jan 2021 17:01:12

US3392065

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

Form: Unblinding

Generated On: 09 Jun 2021 17:23:26

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
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 12:54:26
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.	(b) (4), (b) (6)	08 Apr 2021 19:50:34
' answered with 'Updated' (Site from DM).		
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 19:50:27
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 19:21:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:13:06

US3392065

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

Form: Unblinding

Generated On: 09 Jun 2021 17:23:26

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '11 Jan 2021'	Brenda Lawson (b) (4)	11 Jan 2021 17:01:12

US3392065

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

Form: Unblinding

Generated On: 09 Jun 2021 17:23:26

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Placebo (Placebo)'	Brenda Lawson (b) (4)	11 Jan 2021 17:01:12

US3392065

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

Form: Unblinding

Generated On: 09 Jun 2021 17:23:26

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 02:57:36
User entered 'Placebo (Placebo)'	Brenda Lawson (b) (4)	11 Jan 2021 17:01:12
	(b) (4)	

US3392065

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

Form: Unblinding

Generated On: 09 Jun 2021 17:23:26

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 02:57:36
User entered 'Placebo (Placebo)'	Brenda Lawson (b) (4)	11 Jan 2021 17:01:12
	(b) (4)	

US3392065

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

Form: Unblinding

Generated On: 09 Jun 2021 17:23:26

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	11 Jan 2021 17:01:12

US3392065

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

Form: Unblinding

Generated On: 09 Jun 2021 17:23:26

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered '1'	System	11 Jan 2021 17:01:12

US3392065

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

Form: Unblinding

Generated On: 09 Jun 2021 17:23:26

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered 'I'	System	11 Jan 2021 17:01:12

US3392065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '65' in	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '178' lb	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered '29.68268'	System	11 Jan 2021 17:03:56
DataPoint set to visible.	System	11 Jan 2021 17:01:12

US3392065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '65' in	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '178' lb	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered '29.68268'	System	11 Jan 2021 17:03:56
DataPoint set to visible.	System	11 Jan 2021 17:01:12

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Lawson (b) (4) (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '11 Jan 2021'	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '10:16'	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered '11 Jan 2021 10:16'	System	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '98.4' F	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Oral (Oral)'	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '64'	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered 'bpm'	System	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '16'	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered 'breaths/min'	System	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '140'	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered 'mmHg'	System	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '80'	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered 'mmHg'	System	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '65' in	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '178' lb	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:23:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered '29.68268'	System	11 Jan 2021 17:03:56
DataPoint set to visible.	System	11 Jan 2021 17:01:12

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Lawson (b) (4) (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 20:39:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 20:39:36
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 17:03:56
User entered empty.	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56
	(b) (4)	

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Jan 2021 20:39:36
User entered empty.	Brenda Lawson (b) (4) (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '12:55' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Jan 2021 20:39:36
User entered empty.	Brenda Lawson (b) (4) (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered '11 Jan 2021 12:55'	System	11 Jan 2021 20:39:36
User entered empty.	System	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '99.1' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Jan 2021 20:39:36
User entered empty.	Brenda Lawson (b) (4) (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Jan 2021 20:39:36
User entered empty.	Brenda Lawson (b) (4) (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	Brenda Lawson (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '60' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Jan 2021 20:39:36
User entered empty.	Brenda Lawson (b) (4) (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered 'bpm'	System	11 Jan 2021 20:39:36
User entered empty.	System	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '14' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Jan 2021 20:39:36
User entered empty.	Brenda Lawson (b) (4) (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered 'breaths/min'	System	11 Jan 2021 20:39:36
User entered empty.	System	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '169' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Jan 2021 20:39:36
User entered empty.	Brenda Lawson (b) (4) (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered 'mmHg'	System	11 Jan 2021 20:39:36
User entered empty.	System	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '91' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Jan 2021 20:39:36
User entered empty.	Brenda Lawson (b) (4) (b) (4)	11 Jan 2021 17:03:56

US3392065

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered 'mmHg'	System	11 Jan 2021 20:39:36
User entered empty.	System	11 Jan 2021 17:03:56

US3392065

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	11 Jan 2021 17:02:15

US3392065

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '11 Jan 2021'	Brenda Lawson (b) (4)	11 Jan 2021 17:02:15

US3392065

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

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	11 Jan 2021 18:04:46

US3392065

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

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	Brenda Lawson (b) (4)	11 Jan 2021 18:04:46

US3392065

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

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	Brenda Lawson (b) (4)	11 Jan 2021 18:04:46

US3392065

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

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered 'mRNA-1273'	System	11 Jan 2021 18:04:46
DataPoint set to visible.	System	11 Jan 2021 17:01:12

US3392065

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

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '11 Jan 2021'	Brenda Lawson (b) (4)	11 Jan 2021 18:04:46

US3392065

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

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '11:20'	Brenda Lawson (b) (4)	11 Jan 2021 18:04:46

US3392065

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

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered '11 Jan 2021 11:20'	System	11 Jan 2021 18:04:46

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

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Left Arm (LEFT ARM)'	Brenda Lawson (b) (4)	11 Jan 2021 18:04:46

US3392065

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

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered 'ONCE'	System	11 Jan 2021 18:04:46

US3392065

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

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered 'INTRAMUSCULAR'	System	11 Jan 2021 18:04:46

US3392065

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	11 Jan 2021 17:01:48

US3392065

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '11 Jan 2021'	Brenda Lawson (b) (4)	11 Jan 2021 17:01:48

US3392065

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '10:25'	Brenda Lawson (b) (4)	11 Jan 2021 17:01:48

US3392065

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered '11 Jan 2021 10:25'	System	11 Jan 2021 17:01:48

US3392065

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:23:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	11 Jan 2021 17:04:30

US3392065

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:23:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '11 Jan 2021'	Brenda Lawson (b) (4)	11 Jan 2021 17:04:30

US3392065

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:23:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '10:27'	Brenda Lawson (b) (4)	11 Jan 2021 17:04:30

US3392065

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered '11 Jan 2021 10:27'	System	11 Jan 2021 17:04:30

US3392065

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

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	11 Jan 2021 18:05:01

US3392065

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

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:35
User entered 'I'	System	11 Jan 2021 18:05:01

US3392065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:19:34
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:54:20

US3392065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:19:34
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:54:20

US3392065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:19:34
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:54:20

US3392065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:19:34
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:54:20

US3392065

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:19:34
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:54:26

US3392065

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:19:34
User entered 'I'	System	20 Jan 2021 00:54:26

US3392065

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:19:34
User entered '1'	System	20 Jan 2021 00:54:26
DataPoint set to visible.	System	20 Jan 2021 00:54:26

US3392065

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4)	06 Feb 2021 00:24:12
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '05 Feb 2021'	(b) (4)	06 Feb 2021 00:24:12
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Clinic (Clinic)'	(b) (4)	06 Feb 2021 00:24:12
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered 'OLD29'	System	06 Feb 2021 00:24:12

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User accepted default value 'Pre-Dose (PREDOSE)'	Brandon Illickal (b) (4)	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '05 Feb 2021'	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '09:30'	(b) (4)	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered '05 Feb 2021 09:30'	System	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '98.4' F	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Oral (Oral)'	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '58'	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered 'bpm'	System	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '15'	(b) (4)	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered 'breaths/min'	System	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '165'	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered 'mmHg'	System	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:00:45
User entered '94' reason for change: Data Entry Error	Brandon Illickal (b) (4)	06 Feb 2021 00:26:29
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Brandon Illickal (b) (4)	06 Feb 2021 00:25:44
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		06 Feb 2021 00:25:34
User entered '58'	Brandon Illickal (b) (4)	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:23:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered 'mmHg'	System	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User accepted default value 'Post-Dose (POSTDOSE)'	Brandon Illickal (b) (4)	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '05 Feb 2021'	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '11:22'	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered '05 Feb 2021 11:22'	System	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '98.2' F	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Oral (Oral)'	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '59'	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered 'bpm'	System	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '14'	(b) (4)	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered 'breaths/min'	System	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '136'	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered 'mmHg'	System	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '85'	(b) (4)	06 Feb 2021 00:25:34
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered 'mmHg'	System	06 Feb 2021 00:25:34

US3392065

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'No (N)'	(b) (4)	06 Feb 2021 00:26:41
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4)	06 Feb 2021 00:26:41

US3392065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4)	06 Feb 2021 00:27:03
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4)	06 Feb 2021 00:27:03
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4)	06 Feb 2021 00:27:03
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered 'mRNA-1273'	System	06 Feb 2021 00:27:03
DataPoint set to visible.	System	20 Jan 2021 00:54:26

US3392065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '05 Feb 2021'	(b) (4)	06 Feb 2021 00:27:03
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '10:51'	(b) (4)	06 Feb 2021 00:27:03
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered '05 Feb 2021 10:51'	System	06 Feb 2021 00:27:03

US3392065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Left Arm (LEFT ARM)'	(b) (4)	06 Feb 2021 00:27:03
	Brandon Illickal (b) (4)	

US3392065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered 'ONCE'	System	06 Feb 2021 00:27:03

US3392065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:23:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered 'INTRAMUSCULAR'	System	06 Feb 2021 00:27:03

US3392065

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4)	06 Feb 2021 00:23:58

US3392065

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:13
User entered 'I'	System	06 Feb 2021 00:23:58

US3392065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:56:06
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	12 Feb 2021 17:52:36

US3392065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:56:06
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '12 Feb 2021'	Heather Salisbury (b) (4)	12 Feb 2021 17:52:36

US3392065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:56:06
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Contact Made (CONTACT MADE)'	Heather Salisbury (b) (4)	12 Feb 2021 17:52:36

US3392065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:23:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:56:06
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	Heather Salisbury (b) (4)	12 Feb 2021 17:52:36

US3392065

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:56:06
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	12 Feb 2021 17:52:40

US3392065

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:23:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:56:06
User entered 'I'	System	12 Feb 2021 17:52:40

US3392065

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:14:58

US3392065

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:14:58

US3392065

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:14:58

US3392065

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:23:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User entered 'OLD57'	System	03 Mar 2021 21:14:58

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User entered empty.	System	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User entered empty.	System	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User entered empty.	System	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User entered empty.	System	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User entered empty.	System	03 Mar 2021 21:15:07

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21

US3392065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:23:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21

US3392065

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:12

US3392065

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:23:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:12

US3392065

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:22

US3392065

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:22

US3392065

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:15:03
User entered '10:25'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:15:22

US3392065

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:21
User entered '3 Mar 2021 10:25'	System	03 Mar 2021 21:15:22

US3392065

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:23:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:47
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary DOSE 1, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:17:46
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary DOSE 1, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 14:48:20
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary DOSE 1, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 07:41:06
User entered 'Yes (Y)'	Heather Salisbury (b) (4) (b) (4)	16 Nov 2020 22:44:37

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 16:38:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 16:38:56
	(b) (4)	
Data point term sent to Coder	System	09 Dec 2020 16:37:51
User entered 'Injection Site pain'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'No (N)'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to "No". Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 13:55:02
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to "No". Else, provide clarification.' answered with 'Updated query.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 23:36:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 23:36:34
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to "No". Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 07:23:24
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'No (N)'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '15 Sep 2020'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User entered empty.	System	09 Dec 2020 16:37:10

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'No (N)'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '15 Sep 2020'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User entered empty.	System	09 Dec 2020 16:37:10

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'No (N)'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Related (RELATED)'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Related (RELATED)'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'None (NONE)'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'I'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Heather Salisbury (b) (4)	09 Dec 2020 16:37:10
	(b) (4)	

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User entered '0'	System	09 Dec 2020 16:37:10

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12
User entered '0'	System	09 Dec 2020 16:37:10

US3392065

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:23:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:00:26
User entered empty; reason for change New Information	(b) (4), (b) (6)	02 Mar 2021 16:00:26
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 17:44:00
User entered	System	11 Feb 2021 17:43:51
'USA-US119-2021-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	11 Feb 2021 17:43:51

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Acute diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 00:10:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 00:10:54
	(b) (4)	
Data point term sent to Coder	System	11 Feb 2021 00:09:35
User entered 'acute diverticulitis'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '30 Jan 2021'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User entered empty.	System	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '07 Feb 2021'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User entered empty.	System	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Mar 2021 21:50:24
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	11 Feb 2021 00:11:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	01 Mar 2021 21:50:47
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	01 Mar 2021 21:50:24
User entered 'No (N)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Mar 2021 21:50:24
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Feb 2021 00:11:08
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Feb 2021 00:09:30
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Mar 2021 21:50:47
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		11 Feb 2021 00:11:08
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		11 Feb 2021 00:11:08
User entered '1' reason for change: Data Entry Error	Brandon Illickal (b) (4)	11 Feb 2021 00:11:08
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	11 Feb 2021 00:09:30
User entered '0'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	01 Mar 2021 21:50:47
User entered '30 Jan 2021'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	01 Mar 2021 21:50:47
User entered '07 Feb 2021'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	01 Mar 2021 21:50:47
User entered 'No (N)'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'None (NONE)'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'I'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

US3392065

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
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)	02 Mar 2021 15:57:27
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 15:57:20
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 15:57:16
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) (6)	02 Mar 2021 15:57:12
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 'This event was an AE and not an SAE. Data entered in error has been corrected.' (Site from Safety).	Brandon Illickal (b) (4)	01 Mar 2021 21:51:26
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'This event was an AE and not an SAE. Data entered in error has been corrected.' (Site from Safety).	Brandon Illickal (b) (4)	01 Mar 2021 21:51:23

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'This event was an AE and not an SAE. Data entered in error has been corrected.' (Site from Safety).	Brandon Illickal (b) (4)	01 Mar 2021 21:51:21
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 'This event was an AE and not an SAE. Data entered in error has been corrected.' (Site from Safety).	Brandon Illickal (b) (4)	01 Mar 2021 21:51:18
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	01 Mar 2021 21:50:24
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)	19 Feb 2021 05:34:14
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 05:34:03
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 05:33:47
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)	19 Feb 2021 05:33:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Feb 2021 00:13:02
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Feb 2021 00:13:02
User entered 'subject was admitted to hospital with acute diverticulitis. awaiting hospital records and will update when received.' reason for change: Data Entry Error	Brandon Illickal (b) (4)	11 Feb 2021 00:13:02
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Feb 2021 00:09:30
User entered empty.	Brandon Illickal (b) (4)	11 Feb 2021 00:09:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User entered '0'	System	01 Mar 2021 21:50:24
User entered '1'	System	11 Feb 2021 00:09:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User entered '1'	System	11 Feb 2021 00:09:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:23:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:21
User entered '0'	System	11 Feb 2021 00:09:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
User entered	(b) (4)	
'USA-US119-2021-mRNA-1273-P301000009'	System	29 Mar 2021 16:01:12
User entered 'New'	(b) (4), (b) (6)	29 Mar 2021 16:01:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:25:06
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'subject was discharged with a diagnosis of chest pain, improved. Admission diagnoses was chest pain, unspecified' (Site from DM).	Brandon Illickal (b) (4)	16 Apr 2021 22:26:11
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Unspecified chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 22:23:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 22:23:53
Data point term sent to Coder	System	16 Apr 2021 22:23:03
Coding entries removed.	Brandon Illickal (b) (4)	16 Apr 2021 22:22:48
User entered 'CHEST PAIN, unspecified' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Apr 2021 22:22:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 06:08:44
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 19:40:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	26 Mar 2021 19:40:40
Data point term sent to Coder	System	26 Mar 2021 19:40:18
User entered 'chest pain'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '24 Mar 2021'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:39:43
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date has been updated' (Site from Safety).	Brandon Illickal (b) (4)	16 Apr 2021 22:28:30
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	16 Apr 2021 22:28:04
User entered 'No (N)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Apr 2021 22:28:04
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	16 Apr 2021 22:27:50
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 18:04:49
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	16 Apr 2021 22:28:19
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	16 Apr 2021 22:28:19
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	16 Apr 2021 22:27:50
User entered '25 Mar 2021' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Apr 2021 22:27:50
User entered empty.	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	16 Apr 2021 22:27:50
User entered 'Grade 3/Severe (Grade 3/Severe)'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	26 Mar 2021 19:40:01
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	26 Mar 2021 19:39:42
User entered 'Yes (Y)'	Brandon Illickal (b) (4) (b) (4) (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 14:16:46
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'subject is still admitted' (Site from System).	Brandon Illickal (b) (4)	26 Mar 2021 19:40:31
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	26 Mar 2021 19:40:01
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	26 Mar 2021 19:40:01
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	26 Mar 2021 19:40:01
User entered '1' reason for change: Data Entry Error	Brandon Illickal (b) (4)	26 Mar 2021 19:40:01
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	26 Mar 2021 19:39:42
User entered '0'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '24 Mar 2021'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
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)	19 Apr 2021 13:42:03
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 13:40:55
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 'discharge summary has been sent to Moderna' (Site from Safety).	Brandon Illickal (b) (4)	16 Apr 2021 22:28:54
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'hospital discharge date 25MAR2021' (Site from Safety).	Brandon Illickal (b) (4)	16 Apr 2021 22:28:44
User entered '25 Mar 2021' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Apr 2021 22:27:50
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)	05 Apr 2021 18:05:51
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 18:04:30
User entered empty.	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
User closed query 'PV Query: As the last dose of mRNA-1273 was given on 05 Feb 2021, please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:43:22
Query 'PV Query: As the last dose of mRNA-1273 was given on 05 Feb 2021, please update the action taken with mRNA-1273 from none to not applicable.' answered with 'action updated to not applicable' (Site from Safety).	Brandon Illickal (b) (4)	16 Apr 2021 22:35:08
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Apr 2021 22:27:50
User opened query 'PV Query: As the last dose of mRNA-1273 was given on 05 Feb 2021, please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 18:03:25
User entered 'None (NONE)'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	16 Apr 2021 22:33:48
User entered '1' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Apr 2021 22:33:48
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Apr 2021 22:33:29
User entered '0'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:44:30
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no medications given for treatment. subject had a chest xray.' (Site from Safety).	Brandon Illickal (b) (4)	16 Apr 2021 22:33:38
User entered '0' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Apr 2021 22:33:29
User entered '1' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Apr 2021 22:27:50
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 18:06:17
User entered '0'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

US3392065

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
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)	19 Apr 2021 13:47:19
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:25:25
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'no medications given for treatment. subject had a chest xray.' (Site from DM).	Brandon Illickal (b) (4)	16 Apr 2021 22:33:35
User entered '0' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Apr 2021 22:33:29
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)	16 Apr 2021 22:29:18

US3392065

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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)	05 Apr 2021 18:06:34
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 06:08:52
User entered 'I'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

US3392065

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:47:32
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' answered with 'event has resolved' (Site from Safety).	Brandon Illickal (b) (4)	16 Apr 2021 22:29:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Apr 2021 22:28:19
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 18:05:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

US3392065

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

US3392065

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:48:05
User entered 'THE SUBJECT WAS ADMITTED TO THE EMERGENCY DEPARTMENT WITH CHEST PAIN. A chest xray was performed and the subject did not undergo any treatment during admission.' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Apr 2021 22:34:53
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'all medical records have been sent to Moderna' (Site from Safety).	Brandon Illickal (b) (4)	16 Apr 2021 22:29:36
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 18:04:09
User entered 'THE SUBJECT WAS ADMITTED TO THE EMERGENCY DEPARTMENT WITH CHEST PAIN. THE SUBJECT IS STILL ADMITTED AND WILL FOLLOW-UP WITH MEDICAL RECORDS WHEN DISCHARGED.'	Brandon Illickal (b) (4)	26 Mar 2021 19:39:42

US3392065

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Mar 2021 19:39:42

US3392065

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Mar 2021 19:39:42

US3392065

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:23:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 19:39:42

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 14:49:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 14:49:00
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 14:48:11
User entered 'Fatigue'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '23 Aug 2020'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User entered empty.	System	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '10 Sep 2020'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User entered empty.	System	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Related (RELATED)'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'None (NONE)'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:27
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User entered '0'	System	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28
User entered '0'	System	22 Apr 2021 14:47:47

US3392065

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:23:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:49:28

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:23:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:26:47
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User closed query 'Per CDM: Reason for treating pain is recorded as 'yes' for record #3, 4, 5 and 6in Temperature day form under diary dose folder, however, corresponding concomitant medication has not been reported under Prior/Concomitant Medication and Vaccination section of the eCRF. Please review and update else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 10:44:53
Query 'Per CDM: Reason for treating pain is recorded as 'yes' for record #3, 4, 5 and 6in Temperature day form under diary dose folder, however, corresponding concomitant medication has not been reported under Prior/Concomitant Medication and Vaccination section of the eCRF. Please review and update else clarify.' answered with 'medication has been entered' (Site from DM).	Brandon Illickal (b) (4)	03 Sep 2020 13:42:00
User opened query 'Per CDM: Reason for treating pain is recorded as 'yes' for record #3, 4, 5 and 6in Temperature day form under diary dose folder, however, corresponding concomitant medication has not been reported under Prior/Concomitant Medication and Vaccination section of the eCRF. Please review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 18:38:36
User entered 'Yes (Y)' reason for change: New Information	Brandon Illickal (b) (4)	26 Aug 2020 15:00:15
User entered 'No (N)'	Brandon Illickal (b) (4)	21 Aug 2020 15:50:24

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 21:58:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 21:58:48
Data point term sent to Coder	System	02 Sep 2020 21:57:36
User entered 'omeprazole'	Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'Updated MH' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:15:03
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	Heather Salisbury (b) (4) (b) (4)	09 Dec 2020 16:33:23
User entered 'acid reflux'	(b) (4), (b) (6)	03 Oct 2020 14:49:38
	Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
	(b) (4)	
User entered '20'	Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
	(b) (4)	
User entered 'mg (mg)'	Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	02 Sep 2020 21:59:24
User entered 'once daily (QD)' reason for change: Data Entry Error	System	02 Sep 2020 21:59:24
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	Brandon Illickal (b) (4)	02 Sep 2020 21:59:24
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).		
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	02 Sep 2020 21:59:17
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	02 Sep 2020 21:58:26
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	02 Sep 2020 21:58:26
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	02 Sep 2020 21:58:26
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	02 Sep 2020 21:58:13
User entered 'once (ONCE)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	02 Sep 2020 21:58:13
User entered 'once daily (QD)'	Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'Oral (ORAL)'	(b) (4) Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
	(b) (4)	
User entered '22 Aug 2020' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	02 Sep 2020 21:59:17
User entered '24 Aug 2020' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	02 Sep 2020 21:58:13
User entered '23 Aug 2020'	Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	02 Sep 2020 21:58:13
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
	(b) (4)	
User entered '27 Aug 2020' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	02 Sep 2020 21:59:17
User entered '24 Aug 2020' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	02 Sep 2020 21:58:26
User entered '25 Aug 2020' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	02 Sep 2020 21:58:13
User entered empty.	Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
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	02 Sep 2020 21:58:13
User entered 'No (N)' reason for change: Per Query Resolution	System	02 Sep 2020 21:58:13
	Brandon Illickal (b) (4)	02 Sep 2020 21:58:13
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 21:57:05
User entered empty.	Brandon Illickal (b) (4)	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:59:24
User entered empty.	System	02 Sep 2020 21:58:13
User entered '1'	System	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:59:24
User entered empty.	System	02 Sep 2020 21:58:13
User entered '1'	System	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:23:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 21:59:24
User entered empty.	System	02 Sep 2020 21:58:13
User entered '804 (804)'	System	02 Sep 2020 21:57:05

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 15:15:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:15:55
Data point term sent to Coder	System	30 Sep 2020 15:14:49
User entered 'aspirin'	Brandon Illickal (b) (4)	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User closed query 'Per CDM CLR requery: Per previous query response "AE cert recorded"; however there is no AE that matching with this Con med indication. Please review and update. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:15:25
Query 'Per CDM CLR requery: Per previous query response "AE cert recorded"; however, there is no AE that matching with this Con med indication. Please review and update. Thank you. ' answered with 'AE is recorded for this indication' (Site from DM).	Heather Salisbury (b) (4) (b) (4)	09 Dec 2020 16:38:06
User opened query 'Per CDM CLR requery: Per previous query response "AE cert recorded"; however there is no AE that matching with this Con med indication. Please review and update. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 05:57:27
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. Else, provide clarification if this will not be recorded on AE ecrf. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 05:53:01
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. Else, provide clarification if this will not be recorded on AE ecrf. ' answered with 'AE cert recorded' (Site from DM).	Heather Salisbury (b) (4) (b) (4)	16 Nov 2020 22:44:18
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. Else, provide clarification if this will not be recorded on AE ecrf. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:51:14
User entered 'injection site pain'	Brandon Illickal (b) (4)	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '243'	(b) (4) Brandon Illickal (b) (4)	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'mg (mg)'	(b) (4) Brandon Illickal (b) (4)	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered empty.	(b) (4)	30 Sep 2020 15:14:17
	Brandon Illickal (b) (4)	

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'once (ONCE)'	(b) (4) Brandon Illickal (b) (4)	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered empty.	(b) (4)	30 Sep 2020 15:14:17
	Brandon Illickal (b) (4)	

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'Oral (ORAL)'	(b) (4) Brandon Illickal (b) (4)	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered empty.	(b) (4)	30 Sep 2020 15:14:17
	Brandon Illickal (b) (4)	

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '15 Sep 2020'	(b) (4) Brandon Illickal (b) (4)	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '0'	(b) (4) Brandon Illickal (b) (4)	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '15 Sep 2020'	(b) (4) Brandon Illickal (b) (4)	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4 (occurred after 7 days post vaccination). Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 13:58:02
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4 (occurred after 7 days post vaccination). Review and update entry as appropriate.' answered with 'Updated query' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 23:37:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 23:37:50
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4 (occurred after 7 days post vaccination). Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 07:23:43
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User entered empty.	System	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User entered empty.	System	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:23:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:51
User entered empty.	System	30 Sep 2020 15:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 02:15:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 02:15:44
Data point term sent to Coder	System	05 Jan 2021 02:14:44
User entered 'aspirin'	Brandon Illickal (b) (4)	05 Jan 2021 02:14:24

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'No (N)'	(b) (4)	05 Jan 2021 02:14:24
	Brandon Illickal (b) (4)	

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 13:03:43
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'does not meet AE reporting criteria' (Site from DM).	Brandon Illickal (b) (4)	11 Feb 2021 00:13:20

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

[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 timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM). User entered 'headache'	(b) (4), (b) (6) [REDACTED] Brandon Illickal (b) (4) [REDACTED] [REDACTED]	09 Feb 2021 11:24:44 05 Jan 2021 02:14:24

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '162'	(b) (4) Brandon Illickal (b) (4)	05 Jan 2021 02:14:24

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'mg (mg)'	(b) (4) Brandon Illickal (b) (4)	05 Jan 2021 02:14:24

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered empty.	(b) (4)	05 Jan 2021 02:14:24
	Brandon Illickal (b) (4)	

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'once (ONCE)'	(b) (4)	05 Jan 2021 02:14:24
	Brandon Illickal (b) (4)	

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered empty.	(b) (4)	05 Jan 2021 02:14:24
	Brandon Illickal (b) (4)	

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'Oral (ORAL)'	(b) (4)	05 Jan 2021 02:14:24
	Brandon Illickal (b) (4)	

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered empty.	(b) (4)	05 Jan 2021 02:14:24
	Brandon Illickal (b) (4)	

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '20 Sep 2020'	(b) (4)	05 Jan 2021 02:14:24
	Brandon Illickal (b) (4)	

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '0'	(b) (4) Brandon Illickal (b) (4)	05 Jan 2021 02:14:24

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	05 Jan 2021 02:14:24

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '20 Sep 2020'	(b) (4)	05 Jan 2021 02:14:24

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	05 Jan 2021 02:14:24

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User entered empty.	System	05 Jan 2021 02:14:24

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User entered empty.	System	05 Jan 2021 02:14:24

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:23:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:55
User entered empty.	System	05 Jan 2021 02:14:24

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Feb 2021 00:15:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 00:15:45
Data point term sent to Coder	System	11 Feb 2021 00:14:39
User entered 'ciprofloxacin'	Brandon Illickal (b) (4) 	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'No (N)'	(b) (4)	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'acute diverticulitis'	(b) (4) Brandon Illickal (b) (4)	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '500'	(b) (4) Brandon Illickal (b) (4)	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'mg (mg)'	(b) (4) Brandon Illickal (b) (4)	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered empty.	(b) (4)	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'twice daily (BID)'	(b) (4) Brandon Illickal (b) (4)	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered empty.	(b) (4)	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'Oral (ORAL)'	(b) (4)	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered empty.	(b) (4)	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '30 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Brandon Illickal (b) (4)	11 Feb 2021 00:15:58
User entered '07 Feb 2021'	Brandon Illickal (b) (4)	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '0'	(b) (4) Brandon Illickal (b) (4)	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	11 Feb 2021 00:15:58
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '07 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Brandon Illickal (b) (4)	11 Feb 2021 00:15:58
User entered empty.	(b) (4)	
	Brandon Illickal (b) (4)	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'No (N)'	(b) (4)	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User entered '2'	System	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User entered '1'	System	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:23:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:15
User entered '804 (804)'	System	11 Feb 2021 00:14:17

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 12:33:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 12:33:00
Data point term sent to Coder	System	11 Feb 2021 00:15:43
User entered 'flagyl'	Brandon Illickal (b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'No (N)'	(b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'acute diverticulitis'	(b) (4) Brandon Illickal (b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '500'	(b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'mg (mg)'	(b) (4) Brandon Illickal (b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered empty.	(b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'twice daily (BID)'	(b) (4) Brandon Illickal (b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered empty.	(b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'Oral (ORAL)'	(b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered empty.	(b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '30 Jan 2021'	(b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '0'	(b) (4) Brandon Illickal (b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'No (N)'	(b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '07 Feb 2021'	(b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'No (N)'	(b) (4)	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User entered '2'	System	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User entered '1'	System	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:23:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:27:19
User entered '804 (804)'	System	11 Feb 2021 00:15:38

US3392065

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:23:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User closed query 'Per ETRTR: According to SAE page "Chest Pain", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:35:43
Query 'Per ETRTR: According to SAE page "Chest Pain", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' answered with 'pending medical records from patient' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:14:31
User opened query 'Per ETRTR: According to SAE page "Chest Pain", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 00:34:54
User entered 'No (N)'	Brandon Illickal (b) (4)	21 Aug 2020 15:50:33

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'USA-US119-2021-MRNA-1273-P301000006'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
	(b) (4)	
Un-reviewed for Safety.	System	01 Mar 2021 21:50:47
User entered 'No (N)'	System	01 Mar 2021 21:50:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'Yes (Y)'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'No (N)'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'No (N)'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
	(b) (4)	
Un-reviewed for Safety.	System	01 Mar 2021 21:50:47
User entered 'No (N)'	System	01 Mar 2021 21:50:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'Yes (Y)'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'No (N)'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'No (N)'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'No (N)'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'Michael'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'Cotugno'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'US'	(b) (4) System	11 Feb 2021 17:45:02

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Feb 2021 17:45:02

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'USA-US119-2021-MRNA-1273-P301000006'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
	(b) (4)	
Un-reviewed for Safety.	System	01 Mar 2021 21:50:47
User entered 'No (N)'	System	01 Mar 2021 21:50:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'Yes (Y)'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'No (N)'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'No (N)'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
	(b) (4)	
Un-reviewed for Safety.	System	01 Mar 2021 21:50:47
User entered 'No (N)'	System	01 Mar 2021 21:50:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'Yes (Y)'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'No (N)'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'No (N)'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'No (N)'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'Michael'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:44:38
User entered 'Cotugno'	System	11 Feb 2021 17:43:51

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered 'US'	(b) (4) System	11 Feb 2021 17:45:02

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Feb 2021 17:45:02

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:23:26

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '11/Feb/2021 11:44'	(b) (4) System	11 Feb 2021 17:45:02

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:23:26

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 20:04:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:45:02

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered		
'USA-US119-2021-MRNA-1273-P301000009'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'Yes (Y)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'Yes (Y)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'Michael'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'Cotugno'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'US'	System	29 Mar 2021 16:01:26

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 13:51:14
User entered '1'	System	29 Mar 2021 16:01:26

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered		
'USA-US119-2021-MRNA-1273-P301000009'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'Yes (Y)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'Yes (Y)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'Michael'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'Cotugno'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'US'	System	29 Mar 2021 16:01:26

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 13:51:14
User entered '1'	System	29 Mar 2021 16:01:26

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:23:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '29/Mar/2021 11:01'	(b) (4) System	29 Mar 2021 16:01:26

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:23:26

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 20:04:44
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 16:01:26

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered		
'USA-US119-2021-MRNA-1273-P301000009'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'Yes (Y)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'Yes (Y)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'No (N)'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'Michael'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'Cotugno'	System	29 Mar 2021 16:01:12

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:01:32
User entered 'US'	System	29 Mar 2021 16:01:26

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:23:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 13:51:14
User entered '1'	System	29 Mar 2021 16:01:26

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:23:26

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:04:44
User entered '19/Apr/2021 06:51'	(b) (4) System	19 Apr 2021 13:51:14

US3392065

Folder: SAE USA-US119-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:23:26

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 20:04:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:51:14