

US3392251 (Prod: Benchmark Research - Metairie - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:28:30

All time stamps listed in this document are displayed in GMT

US3392251

Form: Participant Creation

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

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Participant ID

US3392251

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

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US3392251

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:20:37

Generated On: 09 Jun 2021 17:28:30

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 03:20:34

Generated On: 09 Jun 2021 17:28:30

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	65
Age Units	YEARS
Age (Derived)	65
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 03:20:36

Generated On: 09 Jun 2021 17:28:30

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

US3392251

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 03:20:36

Generated On: 09 Jun 2021 17:28:30

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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 03:20:37

Generated On: 09 Jun 2021 17:28:30

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 20 Feb 2021 03:20:37

Generated On: 09 Jun 2021 17:28:30

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Feb 2021 03:20:37

Generated On: 09 Jun 2021 17:28:30

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN JAN 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	23 OCT 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	OCT 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 20 Feb 2021 03:20:37

Generated On: 09 Jun 2021 17:28:30

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN DEC 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 20 Feb 2021 03:20:37

Generated On: 09 Jun 2021 17:28:30

Condition	OBESITY
Start date (dd MMM yyyy)	UN JAN 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 03:20:37

Generated On: 09 Jun 2021 17:28:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	12 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:35 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 11:35
Height ( <i>xxx.x</i> )	63.5 in
Weight ( <i>xxx.x</i> )	219.6 lb
BMI ( <i>xxx.x</i> )	38.37026 kg/m <sup>2</sup>
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 03:20:37

Generated On: 09 Jun 2021 17:28:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 20 Feb 2021 03:20:34

Generated On: 09 Jun 2021 17:28:30

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

Is the participant of childbearing potential? Yes ☐  
No ☒

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

If Partner medically sterile or Other, specify \_\_\_\_\_

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN DEC 2000

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 03:20:37

Generated On: 09 Jun 2021 17:28:30

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

WORK IN CLINIC AND SEE PATIENTS, WEAR A MASK.

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**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 03:20:37

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 02:59:33

Generated On: 09 Jun 2021 17:28:30

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 02:59:33

Generated On: 09 Jun 2021 17:28:30

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

What was the participant's randomization number? 190771

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) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

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) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 SEP 2020
Time of assessment (00:00-23:59)	11:59 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 11:59
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 SEP 2020
Time of assessment (00:00-23:59)	12:44 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 12:44
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 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 02:59:33

Generated On: 09 Jun 2021 17:28:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 02:59:31

Generated On: 09 Jun 2021 17:28:30

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 12 SEP 2020

What was the treatment time? (00:00-23:59) 12:13 (24 HR)

Treatment Date and Time (derived) 12 SEP 2020 12:13

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 02:59:31

Generated On: 09 Jun 2021 17:28:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 SEP 2020

Collection time (00:00-23:59)

11:49 (24 HR)

Collection date and time (derived)

12 SEP 2020 11:49



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 02:59:31

Generated On: 09 Jun 2021 17:28:30

Collection date (dd MMM yyyy)			12 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:41	12 SEP 2020 11:41
Nasopharyngeal Swab 2	No		

US3392251

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:59:31

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**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

98.4 °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

12 SEP 2020 12:48

PC Open Date & Time

12 SEP 2020 12:33

PC Close Date & Time

12 SEP 2020 15:03

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**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 98.2 °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	12 SEP 2020 20:04
PC Open Date & Time	12 SEP 2020 15:58
PC Close Date & Time	13 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 16:30

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 21:30

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 21:13

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 22:29

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59



US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

17 SEP 2020 17:08

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:28:30

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 20:33

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:49

PC Open Date & Time

12 SEP 2020 12:33

PC Close Date & Time

12 SEP 2020 15:03

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 20:05

PC Open Date & Time

12 SEP 2020 15:58

PC Close Date & Time

13 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 16:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 21:31

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 21:13

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 22:30

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59



US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 17:09

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 20:33

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**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 ☐

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 12:49
PC Open Date & Time	12 SEP 2020 12:33
PC Close Date & Time	12 SEP 2020 15:03

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**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 ☐

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 20:06
PC Open Date & Time	12 SEP 2020 15:58
PC Close Date & Time	13 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**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 ☒

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:28:30

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 16:32
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59



US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

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 ☒

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 21:31
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**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 ☒

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:28:30

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 21:13
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**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 ☒

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 22:30
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**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 ☒

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:28:30

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 17:09
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59



US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**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 ☒

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 20:34
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3392251

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:12:30

Generated On: 09 Jun 2021 17:28:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392251

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:12:30

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392251

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:39:02

Generated On: 09 Jun 2021 17:28:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392251

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:39:02

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392251

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:19:39

Generated On: 09 Jun 2021 17:28:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392251

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:19:39

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3392251

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 04:47:56

Generated On: 09 Jun 2021 17:28:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 04:47:56

Generated On: 09 Jun 2021 17:28:30

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)	8 OCT 2020
Time of assessment (00:00-23:59)	11:14 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 11:14
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 04:47:56

Generated On: 09 Jun 2021 17:28:30

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	12:37 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 12:37
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3392251

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 04:47:56

Generated On: 09 Jun 2021 17:28:30

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.*

US3392251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 04:47:56

Generated On: 09 Jun 2021 17:28:30

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) 08 OCT 2020

What was the treatment time? (00:00-23:59) 11:54 (24 HR)

Treatment Date and Time (derived) 08 OCT 2020 11:54

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

US3392251

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 04:47:56

Generated On: 09 Jun 2021 17:28:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 OCT 2020

Collection time (00:00-23:59)

11:42 (24 HR)

Collection date and time (derived)

8 OCT 2020 11:42

US3392251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 04:47:55

Generated On: 09 Jun 2021 17:28:30

Collection date (dd MMM yyyy)			8 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:37	8 OCT 2020 11:37
Nasopharyngeal Swab 2	No		

US3392251

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 04:47:56

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**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

98.9 °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

08 OCT 2020 12:39

PC Open Date & Time

08 OCT 2020 12:14

PC Close Date & Time

08 OCT 2020 14:44

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**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	08 OCT 2020 19:12
PC Open Date & Time	08 OCT 2020 15:39
PC Close Date & Time	09 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 21:39

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 17:17

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 12:49

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:28:30

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

96.8 °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

13 OCT 2020 02:37

---

PC Open Date & Time

12 OCT 2020 12:00

---

PC Close Date & Time

13 OCT 2020 11:59

---

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**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

13 OCT 2020 19:12

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**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

96.2 °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

14 OCT 2020 23:59

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59



US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**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

08 OCT 2020 12:39

PC Open Date & Time

08 OCT 2020 12:14

PC Close Date & Time

08 OCT 2020 14:44

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**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

08 OCT 2020 19:12

PC Open Date & Time

08 OCT 2020 15:39

PC Close Date & Time

09 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**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

09 OCT 2020 21:40

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**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

10 OCT 2020 17:18

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**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

11 OCT 2020 12:49

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**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

13 OCT 2020 02:38

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**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

13 OCT 2020 19:13

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**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

15 OCT 2020 00:00

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59



US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**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 ☐

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 12:40
PC Open Date & Time	08 OCT 2020 12:14
PC Close Date & Time	08 OCT 2020 14:44

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**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 ☐

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 19:13
PC Open Date & Time	08 OCT 2020 15:39
PC Close Date & Time	09 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**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 ☒

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:28:30

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 21:40
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

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 ☒

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 17:19
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59



US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**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 ☒

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:28:30

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 12:49
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

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 ☒

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 02:38
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**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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US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:28:30

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

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**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 ☒

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

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



US3392251

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:03:06

Generated On: 09 Jun 2021 17:28:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392251

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:03:06

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:46:50

Generated On: 09 Jun 2021 17:28:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392251

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:46:50

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392251

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:29:49

Generated On: 09 Jun 2021 17:28:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392251

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:29:49

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392251

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 05:28:38

Generated On: 09 Jun 2021 17:28:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3392251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 05:28:38

Generated On: 09 Jun 2021 17:28:30

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) \_\_\_\_\_



US3392251

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 05:28:38

Generated On: 09 Jun 2021 17:28:30

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.*

US3392251

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 05:28:38

Generated On: 09 Jun 2021 17:28:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 NOV 2020
Collection time (00:00-23:59)	08:50 (24 HR)
Collection date and time (derived)	12 NOV 2020 08:50

US3392251

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 05:28:38

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

<b>TIMEPOINT</b>	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	12 NOV 2020 15:11:14
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3392251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 07:15:58

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 NOV 2020 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 82

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

No ☒

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 DEC 2020 17:13:48

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59



US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 89

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

No ☒

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 16:28:10

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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	17 DEC 2020 21:34:11
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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

23 DEC 2020 16:07:30

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 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"/>
Have you 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	28 DEC 2020 08:31:01
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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

07 JAN 2021 11:08:10

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 17:47:56
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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

21 JAN 2021 16:29:04

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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

25 JAN 2021 15:33:50

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59



US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 FEB 2021 08:04:41

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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

11 FEB 2021 07:50:27

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 12:00:51

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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

22 FEB 2021 07:36:37

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 19:38:51

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 08:00:39
Patient Cloud Open Date & Time	08 MAR 2021 00:01
Patient Cloud Close Date & Time	12 MAR 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

15 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 MAR 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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

22 MAR 2021 15:37:30

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 12:04:48

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 10:46:37

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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 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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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12 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 APR 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 222

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

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

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

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

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

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

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

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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19 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 APR 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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26 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 APR 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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03 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAY 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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="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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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17 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAY 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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24 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAY 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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31 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUN 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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21 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUN 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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="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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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02 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 AUG 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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09 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 AUG 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	16 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	20 AUG 2021 23:59
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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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30 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 SEP 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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="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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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 ☐



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

<b>TIMEPOINT</b>	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	09 FEB 2021 07:34:24
Patient Cloud Open Date & Time	20 SEP 2021 00:01
Patient Cloud Close Date & Time	24 SEP 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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27 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 OCT 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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



US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 OCT 2021 23:59
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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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="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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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08 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 NOV 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 432

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 NOV 2021 23:59
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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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22 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 NOV 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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="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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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29 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 DEC 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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06 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 DEC 2021 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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03 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JAN 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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10 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JAN 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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17 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JAN 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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24 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JAN 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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31 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 FEB 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 FEB 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 FEB 2022 23:59
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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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="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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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28 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAR 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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07 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAR 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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14 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAR 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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21 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAR 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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28 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 APR 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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04 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 APR 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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11 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 APR 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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18 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 APR 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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



US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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="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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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="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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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09 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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30 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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 <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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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 <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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUN 2022 23:59



US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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="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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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04 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUL 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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11 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUL 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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°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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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18 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUL 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUL 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUL 2022 23:59
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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2022 23:59
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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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="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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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05 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 SEP 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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12 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 SEP 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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19 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

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

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

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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03 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 OCT 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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°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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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



US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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17 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

**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 ☐

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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="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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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[Patient Cloud Open Date & Time](#)

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07 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 NOV 2022 23:59

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US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

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="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"/>

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2022 23:59
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US3392251

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:28:30

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		04 MAR 2021 19:39:23

US3392251

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 23:03:00

Generated On: 09 Jun 2021 17:28:30

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*

US3392251

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 23:03:00

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392251

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392251

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392251

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3392251

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392251

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392251

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392251

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3392251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

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) \_\_\_\_\_

US3392251

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

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.*

US3392251

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	08:35 (24 HR)
Collection date and time (derived)	24 MAR 2021 08:35

US3392251

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3392251**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

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*

**US3392251**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3392251

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:28:30

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"/>

**US3392251**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 17:28:30**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3392251

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

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

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

Visit date (dd MMM yyyy)	14 JAN 2021
--------------------------	-------------

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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US3392251

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

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Date of updated informed consent ( <i>dd MMM yyyy</i> )	14 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> )	14 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

US3392251

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Height	63.0 in
Weight	210.0 lb
BMI (xxx.x)	37.27761

US3392251

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Height	63.0 in
Weight	210.0 lb
BMI (xxx.x)	37.27761
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)	14 JAN 2021
Time of assessment (00:00-23:59)	15:27 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 15:27
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)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG



US3392251

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Height	63.0 in
Weight	210.0 lb
BMI (xxx.x)	37.27761
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)	14 JAN 2021
Time of assessment (00:00-23:59)	16:47 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 16:47
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3392251

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

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

14 JAN 2021

---

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

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US3392251

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

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

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) 14 JAN 2021

What was the treatment time? (00:00-23:59) 16:15 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 16:15

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

US3392251

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

15:47 (24 HR)

Collection date and time (derived)

14 JAN 2021 15:47

US3392251

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	15:49
Collection Date and Time (derived)	14 JAN 2021 15:49

US3392251

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

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392251

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392251

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

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



US3392251

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

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)	8 FEB 2021
Time of assessment (00:00-23:59)	13:21 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 13:21
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)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 FEB 2021
Time of assessment (00:00-23:59)	14:09 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 14:09
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3392251

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

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.*

US3392251

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

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) 8 FEB 2021

What was the treatment time? (00:00-23:59) 13:38 (24 HR)

Treatment Date and Time (derived) 8 FEB 2021 13:38

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

US3392251

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392251

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392251

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3392251

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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

US3392251

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

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) \_\_\_\_\_

US3392251

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

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.*

US3392251

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 MAR 2021
Collection time (00:00-23:59)	13:58 (24 HR)
Collection date and time (derived)	05 MAR 2021 13:58

US3392251

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

AEID	USA-US119-2020-MRNA-1273-P30 1000005
Adverse event	PNEUMONIA
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)	20 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	20 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	22 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

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	

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

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PATIENT PRESENTED TO ER C/O  
COUGH/SOB,FEVER, BODY  
ACHES, FATIGUE. ABRUPT  
ONSET;PROGRESSIVE.  
HYPOXIC/ OXYGEN -  
REQUIRING IN ER. ADMITTED  
TO NON-ICU BED.  
COVID 19 TESTING ( PCR ) X 2  
NEG BY ATTENDING  
HOSPITALIST REPORT.  
CXR C/W PNEUMONIA.

---

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

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US3392251

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

AEID	USA-US119-2020-MRNA-1273-P30 1000012
Adverse event	FEVER
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)	25 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	28 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	PATIENT WAS ADMITTED TO HOSPITAL WITH FEVER. AWAITING MEDICAL RECORDS AND WILL UPDATE WHEN RECEIVED.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	
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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Data signed:** (b) (4) 29 Apr 2021 20:09:34

**Generated On: 09 Jun 2021 17:28:30**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

---

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

Yes ☒

No ☐

---

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

---

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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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US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

Name of Medication TRULICITY

Prophylaxis Yes ☐  
No ☒

Indication DIABETES

Dose per administration 1.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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 20:09:34

Generated On: 09 Jun 2021 17:28:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3392251

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Apr 2021 20:09:34

Generated On: 09 Jun 2021 17:28:30

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3392251

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 09 Jun 2021 17:28:30

Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
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US3392251

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:28:30

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

US3392251

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:28:30

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 ☐

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

SAEID	USA-US119-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

SAEID	USA-US119-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/OCT/2020 16:20
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

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

SAEID	USA-US119-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/NOV/2020 14:41
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

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

SAEID	USA-US119-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/DEC/2020 10:35
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

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

SAEID	USA-US119-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/DEC/2020 09:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

SAEID	USA-US119-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	07/JAN/2021 17:21
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



US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

SAEID	USA-US119-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 20:09:35

Generated On: 09 Jun 2021 17:28:30

SAEID	USA-US119-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	29/DEC/2020 10:08
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

US3392251 (Prod: Benchmark Research - Metairie - PPDS)

**US3392251**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:28:30**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'US3392251'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 16:14:49

US3392251

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 16:55:16

US3392251

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '12 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 16:14:50

US3392251

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'Clinic (Clinic)'	Brenda Lawson (b) (4)	12 Sep 2020 16:55:16

**US3392251**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered 'SCRN'	System	12 Sep 2020 16:55:16



US3392251

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:30

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered (b) (6) 1955'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 16:14:56

US3392251

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered '65'	Brenda Lawson (b) (4)	12 Sep 2020 16:55:53

**US3392251**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:28:30**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered 'YEARS'	System	12 Sep 2020 16:55:53

**US3392251**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:28:30**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered '65'	System	12 Sep 2020 16:56:07

**US3392251**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:28:30**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered 'Female (F)'	Brenda Lawson (b) (4)	12 Sep 2020 16:55:53

US3392251

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brenda Lawson (b) (4)	12 Sep 2020 16:55:53

US3392251

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:30

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered 'I'	Brenda Lawson (b) (4)	12 Sep 2020 16:55:53

US3392251

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered '0'	Brenda Lawson (b) (4)	12 Sep 2020 16:55:53



**US3392251**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:28:30**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered '0'	Brenda Lawson (b) (4)	12 Sep 2020 16:55:53

US3392251

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered '0'	Brenda Lawson (b) (4)	12 Sep 2020 16:55:53

US3392251

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered '0'	Brenda Lawson (b) (4)	12 Sep 2020 16:55:53

**US3392251**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:28:30**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered '0'	Brenda Lawson (b) (4)	12 Sep 2020 16:55:53

US3392251

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:30

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 16:55:53

**US3392251**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:28:30**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered '0'	Brenda Lawson (b) (4)	12 Sep 2020 16:55:53

US3392251

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:30

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered '0'	Brenda Lawson (b) (4)	12 Sep 2020 16:55:53

US3392251

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:30

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '12 Sep 2020'	Brenda Lawson (b) (4)	12 Sep 2020 16:56:07



**US3392251**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered 'Sep 2020'	System	12 Sep 2020 16:56:07

**US3392251**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered '2020'	System	12 Sep 2020 16:56:07

**US3392251**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:28:30**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'Amendment 3 (3)'	Brenda Lawson (b) (4)	12 Sep 2020 16:56:07

US3392251

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 16:56:07

**US3392251**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 16:56:07

US3392251

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 16:56:07

US3392251

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 16:56:07

US3392251

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 16:14:50



US3392251

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered 'I'	System	12 Sep 2020 16:56:14

US3392251

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 16:56:14

US3392251

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:28:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 16:56:20

US3392251

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User closed query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:23:58
Query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	14 Jan 2021 23:58:00
User opened query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 02:34:26
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 01:06:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 01:06:00
Data point term sent to Coder	System	17 Dec 2020 01:04:47
User entered 'Diabetes'	(b) (4), (b) (6)	17 Dec 2020 01:04:28

**US3392251**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'UN Jan 2010'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 01:04:28

**US3392251**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 01:04:28

**US3392251**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 01:04:28

**US3392251**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 01:04:28



**US3392251**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 01:04:28

**US3392251**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered 'Jan 2010'	System	17 Dec 2020 01:04:28

**US3392251**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered '2010'	System	17 Dec 2020 01:04:28

**US3392251**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered empty.	System	17 Dec 2020 01:04:28

**US3392251**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered empty.	System	17 Dec 2020 01:04:28

US3392251

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User closed query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:24:02
Query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	14 Jan 2021 23:57:36
User opened query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 02:35:22
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 01:08:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 01:08:01
Data point term sent to Coder	System	17 Dec 2020 01:06:48
User entered 'Hypertension'	(b) (4), (b) (6)	17 Dec 2020 01:06:43

**US3392251**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'UN Jan 2010'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 01:06:43

**US3392251**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 01:06:43



**US3392251**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 01:06:43

US3392251

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 01:06:43

US3392251

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 01:06:43

US3392251

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:30

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered 'Jan 2010'	System	17 Dec 2020 01:06:43

**US3392251**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered '2010'	System	17 Dec 2020 01:06:43

**US3392251**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered 'Oct 2020'	System	17 Dec 2020 01:06:43

**US3392251**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered '2020'	System	17 Dec 2020 01:06:43

US3392251

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
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)	05 Jan 2021 17:47:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Jan 2021 17:47:31
Data point term sent to Coder	System	05 Jan 2021 17:47:18
User entered 'post-menopausal'	Brandon Illickal (b) (4)	05 Jan 2021 17:47:03



US3392251

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'un Dec 2000'	(b) (4)	05 Jan 2021 17:47:03
	Brandon Illickal (b) (4)	

**US3392251**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:28:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '0'	(b) (4) Brandon Illickal (b) (4)	05 Jan 2021 17:47:03

**US3392251**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:28:30**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'Yes (Y)'	(b) (4)	05 Jan 2021 17:47:03

**US3392251**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered empty.	(b) (4)	05 Jan 2021 17:47:03
	Brandon Illickal (b) (4)	

US3392251

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '0'	(b) (4)	05 Jan 2021 17:47:03

**US3392251**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered 'Dec 2000'	System	05 Jan 2021 17:47:03

**US3392251**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered '2000'	System	05 Jan 2021 17:47:03

**US3392251**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered empty.	System	05 Jan 2021 17:47:03



**US3392251**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered empty.	System	05 Jan 2021 17:47:03

US3392251

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Jan 2021 21:37:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Jan 2021 21:37:30
Data point term sent to Coder	System	06 Jan 2021 21:36:59
User entered 'OBESITY'	(b) (4), (b) (6)	06 Jan 2021 21:36:58

**US3392251**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'UN Jan 1970'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:36:58

**US3392251**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:28:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:36:58

**US3392251**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:28:30**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:36:58

**US3392251**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:36:58

US3392251

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:36:58

**US3392251**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered 'Jan 1970'	System	06 Jan 2021 21:36:58



**US3392251**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered '1970'	System	06 Jan 2021 21:36:58

**US3392251**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered empty.	System	06 Jan 2021 21:36:58

**US3392251**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered empty.	System	06 Jan 2021 21:36:58

US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 16:57:27

US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '12 Sep 2020'	Brenda Lawson (b) (4)	12 Sep 2020 16:57:27

US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '11:35'	Brenda Lawson (b) (4)	12 Sep 2020 16:57:27

**US3392251**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered '12 Sep 2020 11:35'	System	12 Sep 2020 16:57:27

US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '63.5' in	Brenda Lawson (b) (4)	12 Sep 2020 16:57:27
DataPoint set to visible.	System	12 Sep 2020 16:56:14



US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '219.6' lb	Brenda Lawson (b) (4)	12 Sep 2020 16:57:27
DataPoint set to visible.	System	12 Sep 2020 16:56:14

US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered '38.37026'	System	12 Sep 2020 16:57:27
DataPoint set to visible.	System	12 Sep 2020 16:56:14

**US3392251**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered 'kg/m2'	System	12 Sep 2020 16:57:27
DataPoint set to visible.	System	12 Sep 2020 16:56:14

US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:24:08
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	29 Sep 2020 19:56:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 19:56:37
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 19:34:14
User entered '98.9' F	Brenda Lawson (b) (4)	12 Sep 2020 16:57:27

US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered empty; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 19:56:37
User entered 'Oral (Oral)'	(b) (4) Brenda Lawson (b) (4)	12 Sep 2020 16:57:27

**US3392251**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 16:57:27

US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 19:56:37
User entered '68'	Brenda Lawson (b) (4)	12 Sep 2020 16:57:27

**US3392251**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered 'bpm'	System	12 Sep 2020 16:57:27



US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 19:56:37
User entered '14'	Brenda Lawson (b) (4)	12 Sep 2020 16:57:27

US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered 'breaths/min'	System	12 Sep 2020 16:57:27

US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 19:56:37
User entered '113'	(b) (4) Brenda Lawson (b) (4)	12 Sep 2020 16:57:27

US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered 'mmHg'	System	12 Sep 2020 16:57:27

US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 19:56:37
User entered '71'	Brenda Lawson (b) (4)	12 Sep 2020 16:57:27

US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User entered 'mmHg'	System	12 Sep 2020 16:57:27

US3392251

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26

**US3392251**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26



**US3392251**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:28:30**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 16:57:37

US3392251

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '12 Sep 2020'	Brenda Lawson (b) (4)	12 Sep 2020 16:57:37

US3392251

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:28:30

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	05 Jan 2021 17:46:28
User entered '12 Sep 2020' reason for change: Data Entry Error	System	05 Jan 2021 17:46:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Brandon Illickal (b) (4)	05 Jan 2021 17:46:28
User entered 'un Dec 2000' (non-conformant).	System	05 Jan 2021 17:45:33
User entered '12 Sep 2020'	Brandon Illickal (b) (4)	05 Jan 2021 17:45:33
	Brenda Lawson (b) (4)	12 Sep 2020 16:57:58
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 16:57:58

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:28:30

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
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)	06 Jan 2021 15:46:33
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 in MH' (Site from DM).	Brandon Illickal (b) (4)	05 Jan 2021 17:39:51
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)	09 Oct 2020 12:59:52
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Brenda Lawson (b) (4)	12 Sep 2020 16:57:58

US3392251

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:28:30

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 16:57:58

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 16:57:58

**US3392251**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:28:30**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered '0'	Brenda Lawson (b) (4)	12 Sep 2020 16:57:58



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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered 'un Dec 2000' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	05 Jan 2021 17:46:28
User entered empty.	(b) (4) Brenda Lawson (b) (4)	12 Sep 2020 16:57:58

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:28:30

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:34
User entered '0' reason for change: Data Entry Error	(b) (4)	05 Jan 2021 17:46:28
User entered '1'	Brenda Lawson (b) (4)	12 Sep 2020 16:57:58

US3392251

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

US3392251

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 17:28:30**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'Work in clinic and see patients, Wear a mask.'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '0'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03



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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '0'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '0'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered 'I'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '0'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '0'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered '0'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:01:26
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:20:37
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 16:59:03

US3392251

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:28:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:17



**US3392251**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered '12 Sep 2020'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:17

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered 'Clinic (Clinic)'	Brenda Lawson (b) (4)	12 Sep 2020 16:59:17

**US3392251**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'VISIT1'	System	12 Sep 2020 16:59:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered '12 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 16:59:15

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered '190771'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 16:59:15

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Sep 2020 16:59:15

US3392251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:30

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 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 17:09:01

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:30

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 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 17:09:01



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 17:09:01

**US3392251**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:28:30**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 17:09:01

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 17:09:01

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:30

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:21:56
Query 'Per CDM: This field requires a Yes or No response. Please complete. ' answered with 'Updated query' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 00:17:40
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 00:17:32
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 16:53:02
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:05:55
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:05:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
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 18:24:11
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)	29 Sep 2020 17:34:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 17:33:58
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 19:34:23
User entered '63.3' in	Brenda Lawson (b) (4) (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 17:33:58
User entered '219.6' lb	Brenda Lawson (b) (4) (b) (4)	12 Sep 2020 17:12:44

US3392251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
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 18:24:11
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)	29 Sep 2020 17:34:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 17:33:58
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 19:34:23
User entered '63.3' in	Brenda Lawson (b) (4) (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 17:33:58
User entered '219.6' lb	Brenda Lawson (b) (4) (b) (4)	12 Sep 2020 17:12:44



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Lawson (b) (4) (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered '12 Sep 2020'	Brenda Lawson (b) (4)	12 Sep 2020 17:12:44

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered '11:59'	Brenda Lawson (b) (4)	12 Sep 2020 17:12:44

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered '12 Sep 2020 11:59'	System	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered '98.9' F	Brenda Lawson (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered 'Oral (Oral)'	Brenda Lawson (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 17:12:44



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Dec 2020 19:49:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	15 Dec 2020 19:49:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 19:49:10
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Sep 2020 17:12:44
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 17:12:44
	(b) (4)	

**US3392251**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'bpm'	System	15 Dec 2020 19:49:10
User entered empty.	System	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Dec 2020 19:49:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	15 Dec 2020 19:49:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 19:49:10
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Sep 2020 17:12:44
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 17:12:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'breaths/min'	System	15 Dec 2020 19:49:10
User entered empty.	System	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Dec 2020 19:49:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	15 Dec 2020 19:49:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 19:49:10
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Sep 2020 17:12:44
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 17:12:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'mmHg'	System	15 Dec 2020 19:49:10
User entered empty.	System	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Dec 2020 19:49:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	15 Dec 2020 19:49:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 19:49:10
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Sep 2020 17:12:44
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 17:12:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'mmHg'	System	15 Dec 2020 19:49:10
User entered empty.	System	12 Sep 2020 17:12:44



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
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 18:24:11
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)	29 Sep 2020 17:34:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 17:33:58
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 19:34:23
User entered '63.3' in	Brenda Lawson (b) (4) (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 17:33:58
User entered '219.6' lb	Brenda Lawson (b) (4) (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Lawson (b) (4) (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
Signature has been broken.	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 19:50:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 19:50:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 19:50:45
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Sep 2020 17:12:44
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:46:50
Signature has been broken.	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User entered '12 Sep 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered empty.	(b) (4) Brenda Lawson (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:46:50
Signature has been broken.	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User entered '12:44' reason for change: Data Entry Error	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered empty.	(b) (4) Brenda Lawson (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered '12 Sep 2020 12:44'	System	08 Mar 2021 23:41:41
User entered empty.	System	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:46:50
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Mar 2021 23:41:47
User entered '98.4' F reason for change: Data Entry Error	Brandon Illickal (b) (4)	08 Mar 2021 23:41:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Mar 2021 23:41:41
Signature has been broken.	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User entered '98.4.' (non-conformant).	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered empty.	(b) (4) Brenda Lawson (b) (4)	12 Sep 2020 17:12:44



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:46:50
Signature has been broken.	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User entered 'Oral (Oral)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered empty.	(b) (4) Brenda Lawson (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:46:50
Signature has been broken.	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User entered '68' reason for change: Data Entry Error	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered empty.	(b) (4) Brenda Lawson (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'bpm'	System	08 Mar 2021 23:41:41
User entered empty.	System	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:46:50
Signature has been broken.	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User entered '14' reason for change: Data Entry Error	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered empty.	(b) (4) Brenda Lawson (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'breaths/min'	System	08 Mar 2021 23:41:41
User entered empty.	System	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:46:50
Signature has been broken.	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User entered '110' reason for change: Data Entry Error	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered empty.	(b) (4) Brenda Lawson (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'mmHg'	System	08 Mar 2021 23:41:41
User entered empty.	System	12 Sep 2020 17:12:44



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:46:50
Signature has been broken.	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User entered '68' reason for change: Data Entry Error	Brandon Illickal (b) (4)	08 Mar 2021 23:41:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered empty.	(b) (4) Brenda Lawson (b) (4)	12 Sep 2020 17:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:13
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:17:43
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'mmHg'	System	08 Mar 2021 23:41:41
User entered empty.	System	12 Sep 2020 17:12:44

**US3392251**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:28:30**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 17:12:54

**US3392251**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:28:30**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:33
User entered '12 Sep 2020'	Brenda Lawson (b) (4)	12 Sep 2020 17:12:54

US3392251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 17:17:13

US3392251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 17:17:13

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

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 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 17:17:13

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'MRNA-1273 OR PLACEBO'	System	12 Sep 2020 17:17:13



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered '12 Sep 2020'	Brenda Lawson (b) (4)	12 Sep 2020 17:17:13

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered '12:13'	Brenda Lawson (b) (4)	12 Sep 2020 17:17:13

**US3392251**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered '12 Sep 2020 12:13'	System	12 Sep 2020 17:17:13

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered 'Left Arm (LEFT ARM)'	Brenda Lawson (b) (4)	12 Sep 2020 17:17:13

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'ONCE'	System	12 Sep 2020 17:17:13

US3392251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'INTRAMUSCULAR'	System	12 Sep 2020 17:17:13

US3392251

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 17:16:18

US3392251

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered '12 Sep 2020'	Brenda Lawson (b) (4)	12 Sep 2020 17:16:18



**US3392251**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered '11:49'	Brenda Lawson (b) (4)	12 Sep 2020 17:16:18

**US3392251**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered '12 Sep 2020 11:49'	System	12 Sep 2020 17:16:18

US3392251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:28:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered '12 Sep 2020'	Brenda Lawson (b) (4)	12 Sep 2020 17:16:37

**US3392251**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Lawson (b) (4)	12 Sep 2020 17:16:37

US3392251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 17:16:37

**US3392251**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered '11:41'	Brenda Lawson (b) (4)	12 Sep 2020 17:16:37

**US3392251**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered '12 Sep 2020 11:41'	System	12 Sep 2020 17:16:37

**US3392251**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Lawson (b) (4)	12 Sep 2020 17:16:37



US3392251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered 'No (N)'	Brenda Lawson (b) (4)	12 Sep 2020 17:16:37

**US3392251**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered empty.	Brenda Lawson (b) (4)	12 Sep 2020 17:16:37

**US3392251**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered empty.	System	12 Sep 2020 17:16:37

US3392251

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:59:31
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	12 Sep 2020 17:16:43

**US3392251**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'I'	System	12 Sep 2020 17:16:43

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:48:20', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2587b15d-896f-4d9b-bc21-1fd8f8d15aea' User entered 'Yes (Y)'	System	12 Sep 2020 17:48:51
	System	12 Sep 2020 17:48:51

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:48:27', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2587b15d-896f-4d9b-bc21-1fd8f8d15aea' User entered '98.4'	System	12 Sep 2020 17:48:51
	System	12 Sep 2020 17:48:51



US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:48:36', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2587b15d-896f-4d9b-bc21-1fd8f8d15aea' User entered 'No (N)'	System	12 Sep 2020 17:48:51
	System	12 Sep 2020 17:48:51

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:48:48', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2587b15d-896f-4d9b-bc21-1fd8f8d15aea'	System	12 Sep 2020 17:48:51
User entered '12 Sep 2020 12:48'	System	12 Sep 2020 17:48:51

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Sep 2020 12:33'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Sep 2020 15:03'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:04:28', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b7b65db7-1e15-4d85-8c87-b4bde7e14985'	System	13 Sep 2020 01:04:55
User entered 'Yes (Y)'	System	13 Sep 2020 01:04:55

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:04:36', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b7b65db7-1e15-4d85-8c87-b4bde7e14985'	System	13 Sep 2020 01:04:55
User entered '98.2'	System	13 Sep 2020 01:04:55

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:04:40', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b7b65db7-1e15-4d85-8c87-b4bde7e14985'	System	13 Sep 2020 01:04:55
User entered 'No (N)'	System	13 Sep 2020 01:04:55



**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:04:54', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b7b65db7-1e15-4d85-8c87-b4bde7e14985'	System	13 Sep 2020 01:04:55
User entered '12 Sep 2020 20:04'	System	13 Sep 2020 01:04:55

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Sep 2020 15:58'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 2'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:28:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:30:33', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'c99d9b27-5f82-4b74-a89e-eed8709b3e50'	System	13 Sep 2020 21:30:54
User entered 'Yes (Y)'	System	13 Sep 2020 21:30:54

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:30:41', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'c99d9b27-5f82-4b74-a89e-eed8709b3e50'	System	13 Sep 2020 21:30:54
User entered '98.0'	System	13 Sep 2020 21:30:54

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:30:46', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'c99d9b27-5f82-4b74-a89e-eed8709b3e50'	System	13 Sep 2020 21:30:54
User entered 'No (N)'	System	13 Sep 2020 21:30:54

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:30:50', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'c99d9b27-5f82-4b74-a89e-eed8709b3e50'	System	13 Sep 2020 21:30:54
User entered '13 Sep 2020 16:30'	System	13 Sep 2020 21:30:54



US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:28:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 3'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:30:34', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'd519c4b7-ef87-4872-899b-d377d883cb41' User entered 'Yes (Y)'	System	15 Sep 2020 02:30:50
	System	15 Sep 2020 02:30:50

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:30:41', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'd519c4b7-ef87-4872-899b-d377d883cb41' User entered '97.4'	System	15 Sep 2020 02:30:50
	System	15 Sep 2020 02:30:50

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:30:44', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'd519c4b7-ef87-4872-899b-d377d883cb41'	System	15 Sep 2020 02:30:50
User entered 'No (N)'	System	15 Sep 2020 02:30:50

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:30:48', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'd519c4b7-ef87-4872-899b-d377d883cb41'	System	15 Sep 2020 02:30:50
User entered '14 Sep 2020 21:30'	System	15 Sep 2020 02:30:50

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:28:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:17:13



US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:28:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 4'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:28:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:12:47', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b9d94eea-3f2a-4503-98c2-fbe5b62c6ea7' User entered 'Yes (Y)'	System	16 Sep 2020 02:13:15
	System	16 Sep 2020 02:13:15

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:06', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b9d94eea-3f2a-4503-98c2-fbe5b62c6ea7' User entered '97.8'	System	16 Sep 2020 02:13:15
	System	16 Sep 2020 02:13:15

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:09', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b9d94eea-3f2a-4503-98c2-fbe5b62c6ea7'	System	16 Sep 2020 02:13:15
User entered 'No (N)'	System	16 Sep 2020 02:13:15

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:13', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b9d94eea-3f2a-4503-98c2-fbe5b62c6ea7'	System	16 Sep 2020 02:13:15
User entered '15 Sep 2020 21:13'	System	16 Sep 2020 02:13:15

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:28:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:28:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 17:17:13



US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 5'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:28:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:29:33', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'f34facbd-3125-482c-bb03-f681de7961c1' User entered 'Yes (Y)'	System	17 Sep 2020 03:29:52
	System	17 Sep 2020 03:29:52

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:29:43', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'f34facbd-3125-482c-bb03-f681de7961c1' User entered '97.8'	System	17 Sep 2020 03:29:52
	System	17 Sep 2020 03:29:52

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:29:46', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'f34facbd-3125-482c-bb03-f681de7961c1'	System	17 Sep 2020 03:29:52
User entered 'No (N)'	System	17 Sep 2020 03:29:52

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:29:50', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'f34facbd-3125-482c-bb03-f681de7961c1' User entered '16 Sep 2020 22:29'	System	17 Sep 2020 03:29:52
	System	17 Sep 2020 03:29:52

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 6'	System	12 Sep 2020 17:17:13



US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:28:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:08:28', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0cb6be4b-2599-4323-a581-38610d19664c' User entered 'Yes (Y)'	System	17 Sep 2020 22:08:46
	System	17 Sep 2020 22:08:46

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:08:37', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0cb6be4b-2599-4323-a581-38610d19664c' User entered '98.1'	System	17 Sep 2020 22:08:46
	System	17 Sep 2020 22:08:46

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:08:41', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0cb6be4b-2599-4323-a581-38610d19664c'	System	17 Sep 2020 22:08:46
User entered 'No (N)'	System	17 Sep 2020 22:08:46

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:08:44', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0cb6be4b-2599-4323-a581-38610d19664c' User entered '17 Sep 2020 17:08'	System	17 Sep 2020 22:08:46
	System	17 Sep 2020 22:08:46

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 7'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:32:58', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '572b7ac2-0e56-4507-8e36-c6938212711d' User entered 'Yes (Y)'	System	19 Sep 2020 01:33:18
	System	19 Sep 2020 01:33:18



US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:33:06', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '572b7ac2-0e56-4507-8e36-c6938212711d' User entered '97.7'	System	19 Sep 2020 01:33:18
	System	19 Sep 2020 01:33:18

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:33:10', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '572b7ac2-0e56-4507-8e36-c6938212711d' User entered 'No (N)'	System	19 Sep 2020 01:33:18
	System	19 Sep 2020 01:33:18

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:33:15', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '572b7ac2-0e56-4507-8e36-c6938212711d' User entered '18 Sep 2020 20:33'	System	19 Sep 2020 01:33:18
	System	19 Sep 2020 01:33:18

US3392251

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:28:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:48:56', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '6805f395-9944-48d4-b4ce-506dd5f8e93f' User entered 'None (1)'	System	12 Sep 2020 17:49:22
	System	12 Sep 2020 17:49:22

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:48:59', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '6805f395-9944-48d4-b4ce-506dd5f8e93f' User entered 'No (N)'	System	12 Sep 2020 17:49:22
	System	12 Sep 2020 17:49:22



US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:49:03', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '6805f395-9944-48d4-b4ce-506dd5f8e93f' User entered 'No (N)'	System	12 Sep 2020 17:49:22
	System	12 Sep 2020 17:49:22

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:49:10', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '6805f395-9944-48d4-b4ce-506dd5f8e93f' User entered 'None (1)'	System	12 Sep 2020 17:49:22
	System	12 Sep 2020 17:49:22

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:49:19', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '6805f395-9944-48d4-b4ce-506dd5f8e93f' User entered '12 Sep 2020 12:49'	System	12 Sep 2020 17:49:22
	System	12 Sep 2020 17:49:22

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Sep 2020 12:33'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Sep 2020 15:03'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:05:03', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ddb76504-e3ab-46c5-b059-0d8ba9cf8b68'	System	13 Sep 2020 01:05:29
User entered 'None (1)'	System	13 Sep 2020 01:05:29

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:05:07', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ddb76504-e3ab-46c5-b059-0d8ba9cf8b68' User entered 'No (N)'	System	13 Sep 2020 01:05:29
	System	13 Sep 2020 01:05:29



US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:05:12', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ddb76504-e3ab-46c5-b059-0d8ba9cf8b68' User entered 'No (N)'	System	13 Sep 2020 01:05:29
	System	13 Sep 2020 01:05:29

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:05:19', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ddb76504-e3ab-46c5-b059-0d8ba9cf8b68'	System	13 Sep 2020 01:05:29
User entered 'None (1)'	System	13 Sep 2020 01:05:29

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:05:28', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ddb76504-e3ab-46c5-b059-0d8ba9cf8b68' User entered '12 Sep 2020 20:05'	System	13 Sep 2020 01:05:29
	System	13 Sep 2020 01:05:29

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Sep 2020 15:58'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 2'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:30:54', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'f8e4aed1-355a-45f7-a98e-51a8840cd73e'	System	13 Sep 2020 21:31:21
User entered 'None (1)'	System	13 Sep 2020 21:31:21

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:28:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:30:57', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'f8e4aed1-355a-45f7-a98e-51a8840cd73e' User entered 'No (N)'	System	13 Sep 2020 21:31:21
	System	13 Sep 2020 21:31:21



US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:31:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'f8e4aed1-355a-45f7-a98e-51a8840cd73e' User entered 'No (N)'	System	13 Sep 2020 21:31:21
	System	13 Sep 2020 21:31:21

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:31:05', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'f8e4aed1-355a-45f7-a98e-51a8840cd73e' User entered 'None (1)'	System	13 Sep 2020 21:31:21
	System	13 Sep 2020 21:31:21

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:31:15', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'f8e4aed1-355a-45f7-a98e-51a8840cd73e' User entered '13 Sep 2020 16:31'	System	13 Sep 2020 21:31:21
	System	13 Sep 2020 21:31:21

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 3'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:30:54', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e5f79869-33a2-4e46-b816-4d2b582b03f1'	System	15 Sep 2020 02:31:12
User entered 'None (1)'	System	15 Sep 2020 02:31:12

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:28:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:30:58', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e5f79869-33a2-4e46-b816-4d2b582b03f1' User entered 'No (N)'	System	15 Sep 2020 02:31:12
	System	15 Sep 2020 02:31:12



US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:31:03', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e5f79869-33a2-4e46-b816-4d2b582b03f1' User entered 'No (N)'	System	15 Sep 2020 02:31:12
	System	15 Sep 2020 02:31:12

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:31:07', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e5f79869-33a2-4e46-b816-4d2b582b03f1' User entered 'None (1)'	System	15 Sep 2020 02:31:12
	System	15 Sep 2020 02:31:12

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:31:10', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e5f79869-33a2-4e46-b816-4d2b582b03f1' User entered '14 Sep 2020 21:31'	System	15 Sep 2020 02:31:12
	System	15 Sep 2020 02:31:12

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 4'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:19', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'c73815d3-1007-404f-8713-d63b5539b542'	System	16 Sep 2020 02:13:36
User entered 'None (1)'	System	16 Sep 2020 02:13:36

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:28:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:22', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'c73815d3-1007-404f-8713-d63b5539b542'	System	16 Sep 2020 02:13:36
User entered 'No (N)'	System	16 Sep 2020 02:13:36



US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:25', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'c73815d3-1007-404f-8713-d63b5539b542'	System	16 Sep 2020 02:13:36
User entered 'No (N)'	System	16 Sep 2020 02:13:36

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:27', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'c73815d3-1007-404f-8713-d63b5539b542'	System	16 Sep 2020 02:13:36
User entered 'None (1)'	System	16 Sep 2020 02:13:36

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:32', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'c73815d3-1007-404f-8713-d63b5539b542'	System	16 Sep 2020 02:13:36
User entered '15 Sep 2020 21:13'	System	16 Sep 2020 02:13:36

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 5'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:29:56', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'df5d2894-b18d-442a-86cf-2744ca39e8f5'	System	17 Sep 2020 03:30:13
User entered 'None (1)'	System	17 Sep 2020 03:30:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:28:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:29:59', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'df5d2894-b18d-442a-86cf-2744ca39e8f5'	System	17 Sep 2020 03:30:13
User entered 'No (N)'	System	17 Sep 2020 03:30:13



US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:30:02', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'df5d2894-b18d-442a-86cf-2744ca39e8f5'	System	17 Sep 2020 03:30:13
User entered 'No (N)'	System	17 Sep 2020 03:30:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:30:05', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'df5d2894-b18d-442a-86cf-2744ca39e8f5'	System	17 Sep 2020 03:30:13
User entered 'None (1)'	System	17 Sep 2020 03:30:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:30:12', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'df5d2894-b18d-442a-86cf-2744ca39e8f5'	System	17 Sep 2020 03:30:13
User entered '16 Sep 2020 22:30'	System	17 Sep 2020 03:30:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 6'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:08:50', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8169d5af-0483-4df0-b23e-10c9513ddb0f' User entered 'None (1)'	System	17 Sep 2020 22:09:09
	System	17 Sep 2020 22:09:09

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:28:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:08:53', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8169d5af-0483-4df0-b23e-10c9513ddb0f' User entered 'No (N)'	System	17 Sep 2020 22:09:09
	System	17 Sep 2020 22:09:09



US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:08:56', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8169d5af-0483-4df0-b23e-10c9513ddb0f' User entered 'No (N)'	System	17 Sep 2020 22:09:09
	System	17 Sep 2020 22:09:09

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:09:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8169d5af-0483-4df0-b23e-10c9513ddb0f' User entered 'None (1)'	System	17 Sep 2020 22:09:09
	System	17 Sep 2020 22:09:09

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:09:04', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8169d5af-0483-4df0-b23e-10c9513ddb0f' User entered '17 Sep 2020 17:09'	System	17 Sep 2020 22:09:09
	System	17 Sep 2020 22:09:09

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 7'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:33:31', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2a491925-05d3-434f-81c7-8d822093015f' User entered 'None (1)'	System	19 Sep 2020 01:33:50
	System	19 Sep 2020 01:33:50

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:33:36', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2a491925-05d3-434f-81c7-8d822093015f' User entered 'No (N)'	System	19 Sep 2020 01:33:50
	System	19 Sep 2020 01:33:50



US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:33:40', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2a491925-05d3-434f-81c7-8d822093015f' User entered 'No (N)'	System	19 Sep 2020 01:33:50
	System	19 Sep 2020 01:33:50

US3392251

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:33:43', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2a491925-05d3-434f-81c7-8d822093015f' User entered 'None (1)'	System	19 Sep 2020 01:33:50
	System	19 Sep 2020 01:33:50

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:33:48', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2a491925-05d3-434f-81c7-8d822093015f' User entered '18 Sep 2020 20:33'	System	19 Sep 2020 01:33:50
	System	19 Sep 2020 01:33:50

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:49:25', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '046a83e8-d535-43f7-b77d-2301839ac693' User entered 'None (0)'	System	12 Sep 2020 17:49:51
	System	12 Sep 2020 17:49:51

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:49:28', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '046a83e8-d535-43f7-b77d-2301839ac693' User entered 'None (0)'	System	12 Sep 2020 17:49:51
	System	12 Sep 2020 17:49:51



**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:49:31', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '046a83e8-d535-43f7-b77d-2301839ac693' User entered 'None (0)'	System	12 Sep 2020 17:49:51
	System	12 Sep 2020 17:49:51

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:49:34', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '046a83e8-d535-43f7-b77d-2301839ac693' User entered 'None (0)'	System	12 Sep 2020 17:49:51
	System	12 Sep 2020 17:49:51

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:49:36', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '046a83e8-d535-43f7-b77d-2301839ac693' User entered 'None (0)'	System	12 Sep 2020 17:49:51
	System	12 Sep 2020 17:49:51

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:49:38', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '046a83e8-d535-43f7-b77d-2301839ac693' User entered 'None (0)'	System	12 Sep 2020 17:49:51
	System	12 Sep 2020 17:49:51

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:49:41', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '046a83e8-d535-43f7-b77d-2301839ac693' User entered 'No (N)'	System	12 Sep 2020 17:49:51
	System	12 Sep 2020 17:49:51

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T12:49:49', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '046a83e8-d535-43f7-b77d-2301839ac693' User entered '12 Sep 2020 12:49'	System	12 Sep 2020 17:49:51
	System	12 Sep 2020 17:49:51

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Sep 2020 12:33'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Sep 2020 15:03'	System	12 Sep 2020 17:17:13



US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:05:35', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '701aba00-11f1-49d6-8f01-461a57495124' User entered 'None (0)'	System	13 Sep 2020 01:06:04
	System	13 Sep 2020 01:06:04

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:05:38', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '701aba00-11f1-49d6-8f01-461a57495124' User entered 'None (0)'	System	13 Sep 2020 01:06:04
	System	13 Sep 2020 01:06:04

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:05:40', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '701aba00-11f1-49d6-8f01-461a57495124' User entered 'None (0)'	System	13 Sep 2020 01:06:04
	System	13 Sep 2020 01:06:04

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:05:43', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '701aba00-11f1-49d6-8f01-461a57495124' User entered 'None (0)'	System	13 Sep 2020 01:06:04
	System	13 Sep 2020 01:06:04

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:05:46', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '701aba00-11f1-49d6-8f01-461a57495124' User entered 'None (0)'	System	13 Sep 2020 01:06:04
	System	13 Sep 2020 01:06:04

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:05:49', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '701aba00-11f1-49d6-8f01-461a57495124' User entered 'None (0)'	System	13 Sep 2020 01:06:04
	System	13 Sep 2020 01:06:04

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:05:54', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '701aba00-11f1-49d6-8f01-461a57495124' User entered 'No (N)'	System	13 Sep 2020 01:06:04
	System	13 Sep 2020 01:06:04



**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-12T20:06:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '701aba00-11f1-49d6-8f01-461a57495124'	System	13 Sep 2020 01:06:04
User entered '12 Sep 2020 20:06'	System	13 Sep 2020 01:06:04

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Sep 2020 15:58'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 2'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:31:20', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ce3e46bd-29fe-450f-8433-140f002dddbd' User entered 'None (0)'	System	13 Sep 2020 21:32:03
	System	13 Sep 2020 21:32:03

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:31:43', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ce3e46bd-29fe-450f-8433-140f002dddbd' User entered 'None (0)'	System	13 Sep 2020 21:32:03
	System	13 Sep 2020 21:32:03

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:31:47', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ce3e46bd-29fe-450f-8433-140f002dddbd' User entered 'None (0)'	System	13 Sep 2020 21:32:03
	System	13 Sep 2020 21:32:03

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:31:49', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ce3e46bd-29fe-450f-8433-140f002dddbd' User entered 'None (0)'	System	13 Sep 2020 21:32:03
	System	13 Sep 2020 21:32:03



**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:31:52', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ce3e46bd-29fe-450f-8433-140f002dddbd' User entered 'None (0)'	System	13 Sep 2020 21:32:03
	System	13 Sep 2020 21:32:03

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:31:54', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ce3e46bd-29fe-450f-8433-140f002dddbd' User entered 'None (0)'	System	13 Sep 2020 21:32:03
	System	13 Sep 2020 21:32:03

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:31:58', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ce3e46bd-29fe-450f-8433-140f002dddbd'	System	13 Sep 2020 21:32:03
User entered 'No (N)'	System	13 Sep 2020 21:32:03

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-13T16:32:01', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ce3e46bd-29fe-450f-8433-140f002dddbd' User entered '13 Sep 2020 16:32'	System	13 Sep 2020 21:32:03
	System	13 Sep 2020 21:32:03

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 3'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:31:15', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e5629a7f-5e15-4408-831f-e0dc33624037' User entered 'None (0)'	System	15 Sep 2020 02:31:40
	System	15 Sep 2020 02:31:40



US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:31:18', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e5629a7f-5e15-4408-831f-e0dc33624037' User entered 'None (0)'	System	15 Sep 2020 02:31:40
	System	15 Sep 2020 02:31:40

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:31:20', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e5629a7f-5e15-4408-831f-e0dc33624037' User entered 'None (0)'	System	15 Sep 2020 02:31:40
	System	15 Sep 2020 02:31:40

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:31:22', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e5629a7f-5e15-4408-831f-e0dc33624037' User entered 'None (0)'	System	15 Sep 2020 02:31:40
	System	15 Sep 2020 02:31:40

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:31:24', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e5629a7f-5e15-4408-831f-e0dc33624037' User entered 'None (0)'	System	15 Sep 2020 02:31:40
	System	15 Sep 2020 02:31:40

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:31:26', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e5629a7f-5e15-4408-831f-e0dc33624037' User entered 'None (0)'	System	15 Sep 2020 02:31:40
	System	15 Sep 2020 02:31:40

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:31:28', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e5629a7f-5e15-4408-831f-e0dc33624037'	System	15 Sep 2020 02:31:40
User entered 'No (N)'	System	15 Sep 2020 02:31:40

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-14T21:31:36', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e5629a7f-5e15-4408-831f-e0dc33624037'	System	15 Sep 2020 02:31:40
User entered '14 Sep 2020 21:31'	System	15 Sep 2020 02:31:40

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:17:13



**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 4'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:35', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dd17f95-eb25-4727-937c-d803d6021fbc' User entered 'None (0)'	System	16 Sep 2020 02:13:56
	System	16 Sep 2020 02:13:56

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:38', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dd17f95-eb25-4727-937c-d803d6021fbc' User entered 'None (0)'	System	16 Sep 2020 02:13:56
	System	16 Sep 2020 02:13:56

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:40', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dd17f95-eb25-4727-937c-d803d6021fbc' User entered 'None (0)'	System	16 Sep 2020 02:13:56
	System	16 Sep 2020 02:13:56

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:42', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dd17f95-eb25-4727-937c-d803d6021fbc' User entered 'None (0)'	System	16 Sep 2020 02:13:56
	System	16 Sep 2020 02:13:56

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:44', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dd17f95-eb25-4727-937c-d803d6021fbc' User entered 'None (0)'	System	16 Sep 2020 02:13:56
	System	16 Sep 2020 02:13:56

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:47', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dd17f95-eb25-4727-937c-d803d6021fbc' User entered 'None (0)'	System	16 Sep 2020 02:13:56
	System	16 Sep 2020 02:13:56



US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:50', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dd17f95-eb25-4727-937c-d803d6021fbc' User entered 'No (N)'	System	16 Sep 2020 02:13:56
	System	16 Sep 2020 02:13:56

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-15T21:13:53', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dd17f95-eb25-4727-937c-d803d6021fbc' User entered '15 Sep 2020 21:13'	System	16 Sep 2020 02:13:56
	System	16 Sep 2020 02:13:56

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 5'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:30:16', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dc91e85-5c4e-43ca-b5f4-9833b2ddf5d8' User entered 'None (0)'	System	17 Sep 2020 03:30:39
	System	17 Sep 2020 03:30:39

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:30:18', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dc91e85-5c4e-43ca-b5f4-9833b2ddf5d8' User entered 'None (0)'	System	17 Sep 2020 03:30:39
	System	17 Sep 2020 03:30:39

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:30:21', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dc91e85-5c4e-43ca-b5f4-9833b2ddf5d8' User entered 'None (0)'	System	17 Sep 2020 03:30:39
	System	17 Sep 2020 03:30:39



US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:30:23', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dc91e85-5c4e-43ca-b5f4-9833b2ddf5d8' User entered 'None (0)'	System	17 Sep 2020 03:30:39
	System	17 Sep 2020 03:30:39

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:30:25', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dc91e85-5c4e-43ca-b5f4-9833b2ddf5d8' User entered 'None (0)'	System	17 Sep 2020 03:30:39
	System	17 Sep 2020 03:30:39

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:30:28', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dc91e85-5c4e-43ca-b5f4-9833b2ddf5d8' User entered 'None (0)'	System	17 Sep 2020 03:30:39
	System	17 Sep 2020 03:30:39

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:30:30', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dc91e85-5c4e-43ca-b5f4-9833b2ddf5d8' User entered 'No (N)'	System	17 Sep 2020 03:30:39
	System	17 Sep 2020 03:30:39

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-16T22:30:38', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '9dc91e85-5c4e-43ca-b5f4-9833b2ddf5d8' User entered '16 Sep 2020 22:30'	System	17 Sep 2020 03:30:39
	System	17 Sep 2020 03:30:39

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 6'	System	12 Sep 2020 17:17:13



**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:09:08', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '01f17c27-e97a-46b6-a284-9dac70463693' User entered 'None (0)'	System	17 Sep 2020 22:09:28
	System	17 Sep 2020 22:09:28

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:09:10', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '01f17c27-e97a-46b6-a284-9dac70463693' User entered 'None (0)'	System	17 Sep 2020 22:09:28
	System	17 Sep 2020 22:09:28

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:09:12', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '01f17c27-e97a-46b6-a284-9dac70463693' User entered 'None (0)'	System	17 Sep 2020 22:09:28
	System	17 Sep 2020 22:09:28

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:09:15', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '01f17c27-e97a-46b6-a284-9dac70463693' User entered 'None (0)'	System	17 Sep 2020 22:09:28
	System	17 Sep 2020 22:09:28

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:09:17', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '01f17c27-e97a-46b6-a284-9dac70463693' User entered 'None (0)'	System	17 Sep 2020 22:09:28
	System	17 Sep 2020 22:09:28

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:09:19', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '01f17c27-e97a-46b6-a284-9dac70463693' User entered 'None (0)'	System	17 Sep 2020 22:09:28
	System	17 Sep 2020 22:09:28

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:09:22', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '01f17c27-e97a-46b6-a284-9dac70463693' User entered 'No (N)'	System	17 Sep 2020 22:09:28
	System	17 Sep 2020 22:09:28

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-17T17:09:25', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '01f17c27-e97a-46b6-a284-9dac70463693' User entered '17 Sep 2020 17:09'	System	17 Sep 2020 22:09:28
	System	17 Sep 2020 22:09:28



**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 7'	System	12 Sep 2020 17:17:13

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:33:52', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cef71118-50ea-40b2-b594-c700222dd3b5' User entered 'None (0)'	System	19 Sep 2020 01:34:25
	System	19 Sep 2020 01:34:25

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:34:02', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cef71118-50ea-40b2-b594-c700222dd3b5' User entered 'None (0)'	System	19 Sep 2020 01:34:25
	System	19 Sep 2020 01:34:25

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:34:04', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cef71118-50ea-40b2-b594-c700222dd3b5' User entered 'None (0)'	System	19 Sep 2020 01:34:25
	System	19 Sep 2020 01:34:25

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:34:07', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cef71118-50ea-40b2-b594-c700222dd3b5' User entered 'None (0)'	System	19 Sep 2020 01:34:25
	System	19 Sep 2020 01:34:25

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:34:09', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cef71118-50ea-40b2-b594-c700222dd3b5' User entered 'None (0)'	System	19 Sep 2020 01:34:25
	System	19 Sep 2020 01:34:25



US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:34:11', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cef71118-50ea-40b2-b594-c700222dd3b5' User entered 'None (0)'	System	19 Sep 2020 01:34:25
	System	19 Sep 2020 01:34:25

US3392251

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:34:14', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cef71118-50ea-40b2-b594-c700222dd3b5' User entered 'No (N)'	System	19 Sep 2020 01:34:25
	System	19 Sep 2020 01:34:25

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-09-18T20:34:21', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cef71118-50ea-40b2-b594-c700222dd3b5' User entered '18 Sep 2020 20:34'	System	19 Sep 2020 01:34:25
	System	19 Sep 2020 01:34:25

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:12:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:05:04

US3392251

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:12:30
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:05:04

US3392251

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:12:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:05:04



**US3392251**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:12:30
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:05:04

**US3392251**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:12:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:05:09

**US3392251**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'I'	System	08 Oct 2020 17:05:09

**US3392251**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:39:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:05:32

US3392251

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:39:02
User entered '27 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:05:32

US3392251

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:39:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:05:32

**US3392251**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:39:02
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 17:05:32

US3392251

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:39:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:05:41



**US3392251**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'I'	System	08 Oct 2020 17:05:41

**US3392251**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:19:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:06:07

**US3392251**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:19:39
User entered '4 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:06:07

**US3392251**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:19:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:06:07

**US3392251**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:19:39
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:06:07

US3392251

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:19:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:06:14

**US3392251**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:46:50
User entered 'I'	System	08 Oct 2020 17:06:14

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:06:31



**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:06:31

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:06:31

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'VISIT2'	System	08 Oct 2020 17:06:31

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '11:14'	(b) (4), (b) (6)	08 Oct 2020 17:45:24

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered '8 Oct 2020 11:14'	System	08 Oct 2020 17:45:24



US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '98.5' F	(b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:45:24

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '72'	(b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'bpm'	System	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '16'	(b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'breaths/min'	System	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '98'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:45:24



US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'mmHg'	System	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '66'	(b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'mmHg'	System	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:45:24

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '12:37'	(b) (4), (b) (6)	08 Oct 2020 17:45:24

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered '8 Oct 2020 12:37'	System	08 Oct 2020 17:45:24



US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '98.9' F	(b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '72'	(b) (4), (b) (6)	08 Oct 2020 17:45:24

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'bpm'	System	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '16'	(b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'breaths/min'	System	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '97'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:45:24



US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'mmHg'	System	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '63'	(b) (4), (b) (6)	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'mmHg'	System	08 Oct 2020 17:45:24

US3392251

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:06:38

US3392251

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 17:06:38

US3392251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:04

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:28:30**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:04

US3392251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

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)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:04



US3392251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'MRNA-1273 OR PLACEBO'	System	08 Oct 2020 17:07:04

US3392251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:20:18
' (Site from DM).		
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	Brandon Illickal (b) (4)	15 Oct 2020 17:53:49
' answered with 'updated' (Site from DM).		
User entered '08 Oct 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	15 Oct 2020 17:53:40
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4), (b) (6)	15 Oct 2020 16:02:39
' (Site from DM).		
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 17:07:04

US3392251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '11:54'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:04

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered '08 Oct 2020 11:54'	System	15 Oct 2020 17:53:40
User entered '8 Oct 2020 11:54'	System	08 Oct 2020 17:07:04

US3392251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:04

US3392251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'ONCE'	System	08 Oct 2020 17:07:04

US3392251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'INTRAMUSCULAR'	System	08 Oct 2020 17:07:04

US3392251

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:28



US3392251

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:28

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '11:42'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:28

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered '8 Oct 2020 11:42'	System	08 Oct 2020 17:07:28

US3392251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:28:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:55

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Oct 2020 17:07:55

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:55

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered '11:37'	(b) (4), (b) (6)	08 Oct 2020 17:07:55

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered '8 Oct 2020 11:37'	System	08 Oct 2020 17:07:55



**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Oct 2020 17:07:55

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:55

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:55

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered empty.	System	08 Oct 2020 17:07:55

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:47:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:08:01

**US3392251**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'I'	System	08 Oct 2020 17:08:01

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:39:04', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '7ab28db0-6846-4060-a35d-cf0ea1aabcd6' User entered 'Yes (Y)'	System	08 Oct 2020 17:39:23
	System	08 Oct 2020 17:39:23



US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:39:12', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '7ab28db0-6846-4060-a35d-cf0ea1aabcd6' User entered '98.9'	System	08 Oct 2020 17:39:23
	System	08 Oct 2020 17:39:23

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:39:15', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '7ab28db0-6846-4060-a35d-cf0ea1aabcd6'	System	08 Oct 2020 17:39:23
User entered 'No (N)'	System	08 Oct 2020 17:39:23

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:39:19', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '7ab28db0-6846-4060-a35d-cf0ea1aabcd6' User entered '08 Oct 2020 12:39'	System	08 Oct 2020 17:39:23
	System	08 Oct 2020 17:39:23

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '08 Oct 2020 12:14'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '08 Oct 2020 14:44'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:12:09', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '3c86abe2-9d3c-436e-ac1c-3d118753d1e3' User entered 'Yes (Y)'	System	09 Oct 2020 00:12:30
	System	09 Oct 2020 00:12:30

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:12:18', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '3c86abe2-9d3c-436e-ac1c-3d118753d1e3' User entered '98.1'	System	09 Oct 2020 00:12:30
	System	09 Oct 2020 00:12:30



US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:12:23', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '3c86abe2-9d3c-436e-ac1c-3d118753d1e3'	System	09 Oct 2020 00:12:30
User entered 'No (N)'	System	09 Oct 2020 00:12:30

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:12:26', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '3c86abe2-9d3c-436e-ac1c-3d118753d1e3'	System	09 Oct 2020 00:12:30
User entered '08 Oct 2020 19:12'	System	09 Oct 2020 00:12:30

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '08 Oct 2020 15:39'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 2'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:28:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:39:28', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0d8d9788-b1ea-491b-88d0-f104d4659959' User entered 'Yes (Y)'	System	10 Oct 2020 02:39:47
	System	10 Oct 2020 02:39:47

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:39:35', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0d8d9788-b1ea-491b-88d0-f104d4659959' User entered '98.2'	System	10 Oct 2020 02:39:47
	System	10 Oct 2020 02:39:47

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:39:41', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0d8d9788-b1ea-491b-88d0-f104d4659959'	System	10 Oct 2020 02:39:47
User entered 'No (N)'	System	10 Oct 2020 02:39:47



**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:39:44', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0d8d9788-b1ea-491b-88d0-f104d4659959' User entered '09 Oct 2020 21:39'	System	10 Oct 2020 02:39:47
	System	10 Oct 2020 02:39:47

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 3'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:28:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:17:08', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '3f6a7174-3384-479e-8916-5806f8703466' User entered 'Yes (Y)'	System	10 Oct 2020 22:17:25
	System	10 Oct 2020 22:17:25

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:17:17', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '3f6a7174-3384-479e-8916-5806f8703466' User entered '98.0'	System	10 Oct 2020 22:17:25
	System	10 Oct 2020 22:17:25

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:17:20', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '3f6a7174-3384-479e-8916-5806f8703466'	System	10 Oct 2020 22:17:25
User entered 'No (N)'	System	10 Oct 2020 22:17:25

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:28:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:17:23', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '3f6a7174-3384-479e-8916-5806f8703466' User entered '10 Oct 2020 17:17'	System	10 Oct 2020 22:17:25
	System	10 Oct 2020 22:17:25



**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:28:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 4'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:28:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:48:50', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cb5c143e-1ea2-4a88-ba07-3fe8dd9c622f' User entered 'Yes (Y)'	System	11 Oct 2020 17:49:08
	System	11 Oct 2020 17:49:08

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:48:57', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cb5c143e-1ea2-4a88-ba07-3fe8dd9c622f' User entered '97.7'	System	11 Oct 2020 17:49:08
	System	11 Oct 2020 17:49:08

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:01', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cb5c143e-1ea2-4a88-ba07-3fe8dd9c622f' User entered 'No (N)'	System	11 Oct 2020 17:49:08
	System	11 Oct 2020 17:49:08

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:07', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cb5c143e-1ea2-4a88-ba07-3fe8dd9c622f' User entered '11 Oct 2020 12:49'	System	11 Oct 2020 17:49:08
	System	11 Oct 2020 17:49:08

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:28:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 17:07:04



US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:28:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 5'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:28:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:37:33', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'd97260bf-150e-441a-90f4-e95f71e7d253'	System	13 Oct 2020 07:37:53
User entered 'Yes (Y)'	System	13 Oct 2020 07:37:53

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:37:40', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'd97260bf-150e-441a-90f4-e95f71e7d253'	System	13 Oct 2020 07:37:53
User entered '96.8'	System	13 Oct 2020 07:37:53

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:37:45', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'd97260bf-150e-441a-90f4-e95f71e7d253'	System	13 Oct 2020 07:37:53
User entered 'No (N)'	System	13 Oct 2020 07:37:53

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:28:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:37:49', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'd97260bf-150e-441a-90f4-e95f71e7d253'	System	13 Oct 2020 07:37:53
User entered '13 Oct 2020 02:37'	System	13 Oct 2020 07:37:53

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:28:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:28:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 17:07:04



US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 6'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:28:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:12:26', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'a71e8699-30e0-4852-80f6-0aa02418abb3'	System	14 Oct 2020 00:12:46
User entered 'Yes (Y)'	System	14 Oct 2020 00:12:46

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:12:37', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'a71e8699-30e0-4852-80f6-0aa02418abb3' User entered '97.3'	System	14 Oct 2020 00:12:46
	System	14 Oct 2020 00:12:46

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:12:13', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'a71e8699-30e0-4852-80f6-0aa02418abb3'	System	14 Oct 2020 00:12:46
User entered 'No (N)'	System	14 Oct 2020 00:12:46

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:12:44', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'a71e8699-30e0-4852-80f6-0aa02418abb3' User entered '13 Oct 2020 19:12'	System	14 Oct 2020 00:12:46
	System	14 Oct 2020 00:12:46

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 7'	System	08 Oct 2020 17:07:04



US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:28:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-14T23:59:30', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'baffabce-a978-4f43-a3c8-c98c92611d66' User entered 'Yes (Y)'	System	15 Oct 2020 04:59:50
	System	15 Oct 2020 04:59:50

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:28:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-14T23:59:38', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'baffabce-a978-4f43-a3c8-c98c92611d66' User entered '96.2'	System	15 Oct 2020 04:59:50
	System	15 Oct 2020 04:59:50

US3392251

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-14T23:59:42', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'baffabce-a978-4f43-a3c8-c98c92611d66'	System	15 Oct 2020 04:59:50
User entered 'No (N)'	System	15 Oct 2020 04:59:50

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-14T23:59:47', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'baffabce-a978-4f43-a3c8-c98c92611d66'	System	15 Oct 2020 04:59:50
User entered '14 Oct 2020 23:59'	System	15 Oct 2020 04:59:50

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:39:23', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2e3073b0-b39d-4382-a0cd-ea088fe6d5d8'	System	08 Oct 2020 17:39:59
User entered 'None (1)'	System	08 Oct 2020 17:39:59



US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:39:33', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2e3073b0-b39d-4382-a0cd-ea088fe6d5d8'	System	08 Oct 2020 17:39:59
User entered 'No (N)'	System	08 Oct 2020 17:39:59

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:39:36', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2e3073b0-b39d-4382-a0cd-ea088fe6d5d8' User entered 'No (N)'	System	08 Oct 2020 17:39:59
	System	08 Oct 2020 17:39:59

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:39:40', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2e3073b0-b39d-4382-a0cd-ea088fe6d5d8'	System	08 Oct 2020 17:39:59
User entered 'None (1)'	System	08 Oct 2020 17:39:59

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:39:45', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2e3073b0-b39d-4382-a0cd-ea088fe6d5d8' User entered '08 Oct 2020 12:39'	System	08 Oct 2020 17:39:59
	System	08 Oct 2020 17:39:59

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '08 Oct 2020 12:14'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '08 Oct 2020 14:44'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:12:31', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'a8044bfe-df0b-4cec-bb81-a649cd21cfb0'	System	09 Oct 2020 00:12:50
User entered 'None (1)'	System	09 Oct 2020 00:12:50



US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:12:34', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'a8044bfe-df0b-4cec-bb81-a649cd21cfb0'	System	09 Oct 2020 00:12:50
User entered 'No (N)'	System	09 Oct 2020 00:12:50

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:12:37', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'a8044bfe-df0b-4cec-bb81-a649cd21cfb0'	System	09 Oct 2020 00:12:50
User entered 'No (N)'	System	09 Oct 2020 00:12:50

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:12:41', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'a8044bfe-df0b-4cec-bb81-a649cd21cfb0'	System	09 Oct 2020 00:12:50
User entered 'None (1)'	System	09 Oct 2020 00:12:50

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:12:48', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'a8044bfe-df0b-4cec-bb81-a649cd21cfb0' User entered '08 Oct 2020 19:12'	System	09 Oct 2020 00:12:50
	System	09 Oct 2020 00:12:50

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '08 Oct 2020 15:39'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 2'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:39:49', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b02d8924-22d9-4e47-a532-47fdc64086c0'	System	10 Oct 2020 02:40:06
User entered 'None (1)'	System	10 Oct 2020 02:40:06



US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:39:52', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b02d8924-22d9-4e47-a532-47fdc64086c0' User entered 'No (N)'	System	10 Oct 2020 02:40:06
	System	10 Oct 2020 02:40:06

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:39:56', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b02d8924-22d9-4e47-a532-47fdc64086c0' User entered 'No (N)'	System	10 Oct 2020 02:40:06
	System	10 Oct 2020 02:40:06

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:39:59', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b02d8924-22d9-4e47-a532-47fdc64086c0'	System	10 Oct 2020 02:40:06
User entered 'None (1)'	System	10 Oct 2020 02:40:06

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:40:02', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b02d8924-22d9-4e47-a532-47fdc64086c0' User entered '09 Oct 2020 21:40'	System	10 Oct 2020 02:40:06
	System	10 Oct 2020 02:40:06

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 3'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:18:02', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '47f1cbd4-611d-44c6-b1b6-6e2d17daab82'	System	10 Oct 2020 22:18:14
User entered 'None (1)'	System	10 Oct 2020 22:18:14



US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:28:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:18:04', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '47f1cbd4-611d-44c6-b1b6-6e2d17daab82' User entered 'No (N)'	System	10 Oct 2020 22:18:14
	System	10 Oct 2020 22:18:14

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:18:07', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '47f1cbd4-611d-44c6-b1b6-6e2d17daab82' User entered 'No (N)'	System	10 Oct 2020 22:18:14
	System	10 Oct 2020 22:18:14

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:18:10', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '47f1cbd4-611d-44c6-b1b6-6e2d17daab82'	System	10 Oct 2020 22:18:14
User entered 'None (1)'	System	10 Oct 2020 22:18:14

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:18:12', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '47f1cbd4-611d-44c6-b1b6-6e2d17daab82' User entered '10 Oct 2020 17:18'	System	10 Oct 2020 22:18:14
	System	10 Oct 2020 22:18:14

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 4'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:11', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cafb7c88-c85c-4766-90e4-b2d984f79e36'	System	11 Oct 2020 17:49:29
User entered 'None (1)'	System	11 Oct 2020 17:49:29



US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:28:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:13', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cafb7c88-c85c-4766-90e4-b2d984f79e36'	System	11 Oct 2020 17:49:29
User entered 'No (N)'	System	11 Oct 2020 17:49:29

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:17', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cafb7c88-c85c-4766-90e4-b2d984f79e36'	System	11 Oct 2020 17:49:29
User entered 'No (N)'	System	11 Oct 2020 17:49:29

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:22', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cafb7c88-c85c-4766-90e4-b2d984f79e36'	System	11 Oct 2020 17:49:29
User entered 'None (1)'	System	11 Oct 2020 17:49:29

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:25', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'cafb7c88-c85c-4766-90e4-b2d984f79e36'	System	11 Oct 2020 17:49:29
User entered '11 Oct 2020 12:49'	System	11 Oct 2020 17:49:29

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:28:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 5'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:37:53', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8dc358b4-e4de-49d3-993d-b7d0a95c534d'	System	13 Oct 2020 07:38:15
User entered 'None (1)'	System	13 Oct 2020 07:38:15



US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:28:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:37:57', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8dc358b4-e4de-49d3-993d-b7d0a95c534d'	System	13 Oct 2020 07:38:15
User entered 'No (N)'	System	13 Oct 2020 07:38:15

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:38:02', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8dc358b4-e4de-49d3-993d-b7d0a95c534d'	System	13 Oct 2020 07:38:15
User entered 'No (N)'	System	13 Oct 2020 07:38:15

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:38:07', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8dc358b4-e4de-49d3-993d-b7d0a95c534d'	System	13 Oct 2020 07:38:15
User entered 'None (1)'	System	13 Oct 2020 07:38:15

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:38:14', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8dc358b4-e4de-49d3-993d-b7d0a95c534d' User entered '13 Oct 2020 02:38'	System	13 Oct 2020 07:38:15
	System	13 Oct 2020 07:38:15

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 6'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:12:55', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ebd524e9-a16e-40ff-97d5-e76743e50514'	System	14 Oct 2020 00:13:16
User entered 'None (1)'	System	14 Oct 2020 00:13:16



US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:28:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:12:59', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ebd524e9-a16e-40ff-97d5-e76743e50514' User entered 'No (N)'	System	14 Oct 2020 00:13:16
	System	14 Oct 2020 00:13:16

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:13:03', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ebd524e9-a16e-40ff-97d5-e76743e50514' User entered 'No (N)'	System	14 Oct 2020 00:13:16
	System	14 Oct 2020 00:13:16

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:13:06', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ebd524e9-a16e-40ff-97d5-e76743e50514'	System	14 Oct 2020 00:13:16
User entered 'None (1)'	System	14 Oct 2020 00:13:16

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:13:12', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ebd524e9-a16e-40ff-97d5-e76743e50514' User entered '13 Oct 2020 19:13'	System	14 Oct 2020 00:13:16
	System	14 Oct 2020 00:13:16

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 7'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-14T23:59:52', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'aa6f72fa-534f-4918-b116-91611698b872'	System	15 Oct 2020 05:00:10
User entered 'None (1)'	System	15 Oct 2020 05:00:10



US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:28:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-14T23:59:54', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'aa6f72fa-534f-4918-b116-91611698b872'	System	15 Oct 2020 05:00:10
User entered 'No (N)'	System	15 Oct 2020 05:00:10

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-14T23:59:56', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'aa6f72fa-534f-4918-b116-91611698b872' User entered 'No (N)'	System	15 Oct 2020 05:00:10
	System	15 Oct 2020 05:00:10

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-14T23:59:58', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'aa6f72fa-534f-4918-b116-91611698b872'	System	15 Oct 2020 05:00:10
User entered 'None (1)'	System	15 Oct 2020 05:00:10

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-15T00:00:02', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'aa6f72fa-534f-4918-b116-91611698b872'	System	15 Oct 2020 05:00:10
User entered '15 Oct 2020 00:00'	System	15 Oct 2020 05:00:10

US3392251

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:28:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:39:51', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '243a4136-ed97-42ce-a37e-cde70237cae7' User entered 'None (0)'	System	08 Oct 2020 17:40:14
	System	08 Oct 2020 17:40:14



US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:39:57', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '243a4136-ed97-42ce-a37e-cde70237cae7' User entered 'None (0)'	System	08 Oct 2020 17:40:14
	System	08 Oct 2020 17:40:14

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:40:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '243a4136-ed97-42ce-a37e-cde70237cae7' User entered 'None (0)'	System	08 Oct 2020 17:40:14
	System	08 Oct 2020 17:40:14

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:40:03', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '243a4136-ed97-42ce-a37e-cde70237cae7' User entered 'None (0)'	System	08 Oct 2020 17:40:14
	System	08 Oct 2020 17:40:14

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:40:05', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '243a4136-ed97-42ce-a37e-cde70237cae7' User entered 'None (0)'	System	08 Oct 2020 17:40:14
	System	08 Oct 2020 17:40:14

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:40:07', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '243a4136-ed97-42ce-a37e-cde70237cae7' User entered 'None (0)'	System	08 Oct 2020 17:40:14
	System	08 Oct 2020 17:40:14

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:40:10', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '243a4136-ed97-42ce-a37e-cde70237cae7' User entered 'No (N)'	System	08 Oct 2020 17:40:14
	System	08 Oct 2020 17:40:14

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T12:40:12', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '243a4136-ed97-42ce-a37e-cde70237cae7' User entered '08 Oct 2020 12:40'	System	08 Oct 2020 17:40:14
	System	08 Oct 2020 17:40:14

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '08 Oct 2020 12:14'	System	08 Oct 2020 17:07:04



**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '08 Oct 2020 14:44'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:12:57', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4101d8b0-13b3-4244-a604-25f641bea18a' User entered 'None (0)'	System	09 Oct 2020 00:13:18
	System	09 Oct 2020 00:13:18

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:12:59', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4101d8b0-13b3-4244-a604-25f641bea18a' User entered 'None (0)'	System	09 Oct 2020 00:13:18
	System	09 Oct 2020 00:13:18

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:13:01', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4101d8b0-13b3-4244-a604-25f641bea18a' User entered 'None (0)'	System	09 Oct 2020 00:13:18
	System	09 Oct 2020 00:13:18

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:13:03', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4101d8b0-13b3-4244-a604-25f641bea18a' User entered 'None (0)'	System	09 Oct 2020 00:13:18
	System	09 Oct 2020 00:13:18

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:13:05', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4101d8b0-13b3-4244-a604-25f641bea18a' User entered 'None (0)'	System	09 Oct 2020 00:13:18
	System	09 Oct 2020 00:13:18

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:13:07', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4101d8b0-13b3-4244-a604-25f641bea18a' User entered 'None (0)'	System	09 Oct 2020 00:13:18
	System	09 Oct 2020 00:13:18



US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:13:11', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4101d8b0-13b3-4244-a604-25f641bea18a' User entered 'No (N)'	System	09 Oct 2020 00:13:18
	System	09 Oct 2020 00:13:18

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-08T19:13:16', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4101d8b0-13b3-4244-a604-25f641bea18a' User entered '08 Oct 2020 19:13'	System	09 Oct 2020 00:13:18
	System	09 Oct 2020 00:13:18

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '08 Oct 2020 15:39'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 2'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:40:05', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4cfce528-c95e-4a22-a0a3-079f29044c73' User entered 'None (0)'	System	10 Oct 2020 02:40:27
	System	10 Oct 2020 02:40:27

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:40:07', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4cfce528-c95e-4a22-a0a3-079f29044c73' User entered 'None (0)'	System	10 Oct 2020 02:40:27
	System	10 Oct 2020 02:40:27

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:40:09', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4cfce528-c95e-4a22-a0a3-079f29044c73'	System	10 Oct 2020 02:40:27
User entered 'None (0)'	System	10 Oct 2020 02:40:27



US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:28:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:40:12', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4cfce528-c95e-4a22-a0a3-079f29044c73'	System	10 Oct 2020 02:40:27
User entered 'None (0)'	System	10 Oct 2020 02:40:27

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:40:14', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4cfce528-c95e-4a22-a0a3-079f29044c73' User entered 'None (0)'	System	10 Oct 2020 02:40:27
	System	10 Oct 2020 02:40:27

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:40:16', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4cfce528-c95e-4a22-a0a3-079f29044c73' User entered 'None (0)'	System	10 Oct 2020 02:40:27
	System	10 Oct 2020 02:40:27

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:40:19', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4cfce528-c95e-4a22-a0a3-079f29044c73'	System	10 Oct 2020 02:40:27
User entered 'No (N)'	System	10 Oct 2020 02:40:27

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-09T21:40:21', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4cfce528-c95e-4a22-a0a3-079f29044c73'	System	10 Oct 2020 02:40:27
User entered '09 Oct 2020 21:40'	System	10 Oct 2020 02:40:27

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 3'	System	08 Oct 2020 17:07:04



US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:18:21', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0db1906e-0e95-4f02-b12e-f122d4b7c235' User entered 'None (0)'	System	10 Oct 2020 22:19:31
	System	10 Oct 2020 22:19:31

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:18:24', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0db1906e-0e95-4f02-b12e-f122d4b7c235' User entered 'None (0)'	System	10 Oct 2020 22:19:31
	System	10 Oct 2020 22:19:31

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:18:27', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0db1906e-0e95-4f02-b12e-f122d4b7c235' User entered 'None (0)'	System	10 Oct 2020 22:19:31
	System	10 Oct 2020 22:19:31

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:18:29', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0db1906e-0e95-4f02-b12e-f122d4b7c235' User entered 'None (0)'	System	10 Oct 2020 22:19:31
	System	10 Oct 2020 22:19:31

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:18:31', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0db1906e-0e95-4f02-b12e-f122d4b7c235' User entered 'None (0)'	System	10 Oct 2020 22:19:31
	System	10 Oct 2020 22:19:31

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:18:33', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0db1906e-0e95-4f02-b12e-f122d4b7c235' User entered 'None (0)'	System	10 Oct 2020 22:19:31
	System	10 Oct 2020 22:19:31

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:19:21', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0db1906e-0e95-4f02-b12e-f122d4b7c235'	System	10 Oct 2020 22:19:31
User entered 'No (N)'	System	10 Oct 2020 22:19:31

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-10T17:19:28', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0db1906e-0e95-4f02-b12e-f122d4b7c235' User entered '10 Oct 2020 17:19'	System	10 Oct 2020 22:19:31
	System	10 Oct 2020 22:19:31



**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 4'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:29', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2b829dc0-62c2-4823-bc0d-8ff6e7dcee9c' User entered 'None (0)'	System	11 Oct 2020 17:49:52
	System	11 Oct 2020 17:49:52

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:31', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2b829dc0-62c2-4823-bc0d-8ff6e7dcee9c' User entered 'None (0)'	System	11 Oct 2020 17:49:52
	System	11 Oct 2020 17:49:52

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:33', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2b829dc0-62c2-4823-bc0d-8ff6e7dcee9c' User entered 'None (0)'	System	11 Oct 2020 17:49:52
	System	11 Oct 2020 17:49:52

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:35', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2b829dc0-62c2-4823-bc0d-8ff6e7dcee9c' User entered 'None (0)'	System	11 Oct 2020 17:49:52
	System	11 Oct 2020 17:49:52

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:28:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:37', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2b829dc0-62c2-4823-bc0d-8ff6e7dcee9c' User entered 'None (0)'	System	11 Oct 2020 17:49:52
	System	11 Oct 2020 17:49:52



**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:39', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2b829dc0-62c2-4823-bc0d-8ff6e7dcee9c' User entered 'None (0)'	System	11 Oct 2020 17:49:52
	System	11 Oct 2020 17:49:52

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:41', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2b829dc0-62c2-4823-bc0d-8ff6e7dcee9c'	System	11 Oct 2020 17:49:52
User entered 'No (N)'	System	11 Oct 2020 17:49:52

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-11T12:49:49', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '2b829dc0-62c2-4823-bc0d-8ff6e7dcee9c'	System	11 Oct 2020 17:49:52
User entered '11 Oct 2020 12:49'	System	11 Oct 2020 17:49:52

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 5'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:38:19', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8cac17cc-51c8-4046-92e8-61d13be2af04' User entered 'None (0)'	System	13 Oct 2020 07:38:48
	System	13 Oct 2020 07:38:48

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:38:22', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8cac17cc-51c8-4046-92e8-61d13be2af04' User entered 'None (0)'	System	13 Oct 2020 07:38:48
	System	13 Oct 2020 07:38:48



US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:38:24', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8cac17cc-51c8-4046-92e8-61d13be2af04' User entered 'None (0)'	System	13 Oct 2020 07:38:48
	System	13 Oct 2020 07:38:48

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:38:27', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8cac17cc-51c8-4046-92e8-61d13be2af04' User entered 'None (0)'	System	13 Oct 2020 07:38:48
	System	13 Oct 2020 07:38:48

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:38:30', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8cac17cc-51c8-4046-92e8-61d13be2af04' User entered 'None (0)'	System	13 Oct 2020 07:38:48
	System	13 Oct 2020 07:38:48

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:38:33', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8cac17cc-51c8-4046-92e8-61d13be2af04' User entered 'None (0)'	System	13 Oct 2020 07:38:48
	System	13 Oct 2020 07:38:48

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:38:36', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8cac17cc-51c8-4046-92e8-61d13be2af04' User entered 'No (N)'	System	13 Oct 2020 07:38:48
	System	13 Oct 2020 07:38:48

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T02:38:47', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '8cac17cc-51c8-4046-92e8-61d13be2af04' User entered '13 Oct 2020 02:38'	System	13 Oct 2020 07:38:48
	System	13 Oct 2020 07:38:48

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 17:07:04



**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 6'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:13:17', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '1cd0e164-7eee-4aee-89f0-c9fe417eb8f2' User entered 'None (0)'	System	14 Oct 2020 00:13:49
	System	14 Oct 2020 00:13:49

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:13:19', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '1cd0e164-7eee-4aee-89f0-c9fe417eb8f2' User entered 'None (0)'	System	14 Oct 2020 00:13:49
	System	14 Oct 2020 00:13:49

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:13:22', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '1cd0e164-7eee-4aee-89f0-c9fe417eb8f2' User entered 'None (0)'	System	14 Oct 2020 00:13:49
	System	14 Oct 2020 00:13:49

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:13:26', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '1cd0e164-7eee-4aee-89f0-c9fe417eb8f2' User entered 'None (0)'	System	14 Oct 2020 00:13:49
	System	14 Oct 2020 00:13:49

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:28:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:13:28', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '1cd0e164-7eee-4aee-89f0-c9fe417eb8f2' User entered 'None (0)'	System	14 Oct 2020 00:13:49
	System	14 Oct 2020 00:13:49

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:13:31', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '1cd0e164-7eee-4aee-89f0-c9fe417eb8f2' User entered 'None (0)'	System	14 Oct 2020 00:13:49
	System	14 Oct 2020 00:13:49

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:13:41', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '1cd0e164-7eee-4aee-89f0-c9fe417eb8f2' User entered 'No (N)'	System	14 Oct 2020 00:13:49
	System	14 Oct 2020 00:13:49



**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-13T19:13:44', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '1cd0e164-7eee-4aee-89f0-c9fe417eb8f2' User entered '13 Oct 2020 19:13'	System	14 Oct 2020 00:13:49
	System	14 Oct 2020 00:13:49

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	08 Oct 2020 17:07:04
User entered 'Day 7'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-15T00:00:06', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '56b193ab-8e5b-49d1-b9d1-1746b5e89b6e' User entered 'None (0)'	System	15 Oct 2020 05:00:37
	System	15 Oct 2020 05:00:37

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-15T00:00:08', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '56b193ab-8e5b-49d1-b9d1-1746b5e89b6e' User entered 'None (0)'	System	15 Oct 2020 05:00:37
	System	15 Oct 2020 05:00:37

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-15T00:00:11', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '56b193ab-8e5b-49d1-b9d1-1746b5e89b6e' User entered 'None (0)'	System	15 Oct 2020 05:00:37
	System	15 Oct 2020 05:00:37

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-15T00:00:13', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '56b193ab-8e5b-49d1-b9d1-1746b5e89b6e' User entered 'None (0)'	System	15 Oct 2020 05:00:37
	System	15 Oct 2020 05:00:37



**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-15T00:00:15', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '56b193ab-8e5b-49d1-b9d1-1746b5e89b6e' User entered 'None (0)'	System	15 Oct 2020 05:00:37
	System	15 Oct 2020 05:00:37

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-15T00:00:17', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '56b193ab-8e5b-49d1-b9d1-1746b5e89b6e' User entered 'None (0)'	System	15 Oct 2020 05:00:37
	System	15 Oct 2020 05:00:37

US3392251

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:28:30

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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-15T00:00:22', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '56b193ab-8e5b-49d1-b9d1-1746b5e89b6e' User entered 'No (N)'	System	15 Oct 2020 05:00:37
	System	15 Oct 2020 05:00:37

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-10-15T00:00:32', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '56b193ab-8e5b-49d1-b9d1-1746b5e89b6e' User entered '15 Oct 2020 00:00'	System	15 Oct 2020 05:00:37
	System	15 Oct 2020 05:00:37

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:28:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 17:07:04

**US3392251**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:03:06
User entered 'Yes (Y)'	(b) (4) Lois Eaglin (b) (4)	26 Oct 2020 14:11:47

**US3392251**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:03:06
User entered '15 Oct 2020'	(b) (4) Lois Eaglin (b) (4)	26 Oct 2020 14:11:47



US3392251

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:03:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lois Eaglin (b) (4)	26 Oct 2020 14:11:47

US3392251

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:03:06
User entered empty.	(b) (4) Lois Eaglin (b) (4)	26 Oct 2020 14:11:47

US3392251

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:03:06
User entered 'Yes (Y)'	(b) (4) Lois Eaglin (b) (4)	26 Oct 2020 14:11:54

**US3392251**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'I'	System	26 Oct 2020 14:11:54

US3392251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:46:50
User entered 'Yes (Y)'	(b) (4) Lois Eaglin (b) (4)	26 Oct 2020 14:12:15

US3392251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:46:50
User entered '22 Oct 2020'	(b) (4) Lois Eaglin (b) (4)	26 Oct 2020 14:12:15

US3392251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:46:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lois Eaglin (b) (4)	26 Oct 2020 14:12:15

US3392251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:46:50
User entered empty.	(b) (4) Lois Eaglin (b) (4)	26 Oct 2020 14:12:15



US3392251

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:46:50
User entered 'Yes (Y)'	(b) (4) Lois Eaglin (b) (4)	27 Oct 2020 14:05:30

**US3392251**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'I'	System	27 Oct 2020 14:05:30

**US3392251**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:29:49
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	12 Nov 2020 14:53:04

US3392251

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:29:49
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 10:18:48
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Hurricane Zeta Delay' (Site from System).	Heather Salisbury (b) (4) (b) (4)	12 Nov 2020 14:53:17
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Nov 2020 14:53:04
User entered '02 Nov 2020'	Heather Salisbury (b) (4) (b) (4)	12 Nov 2020 14:53:04

**US3392251**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:29:49
User entered 'Contact Made (CONTACT MADE)'	Heather Salisbury (b) (4)	12 Nov 2020 14:53:04

**US3392251**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:29:49
User entered empty.	Heather Salisbury (b) (4)	12 Nov 2020 14:53:04

US3392251

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:29:49
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	12 Nov 2020 14:53:26

**US3392251**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'I'	System	12 Nov 2020 14:53:26



**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered 'Yes (Y)'	(b) (4) Heather Salisbury (b) (4)	12 Nov 2020 14:53:58

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered '12 Nov 2020'	(b) (4) Heather Salisbury (b) (4)	12 Nov 2020 14:53:58

US3392251

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered 'Clinic (Clinic)'	Heather Salisbury (b) (4)	12 Nov 2020 14:53:58

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'VISIT3'	System	12 Nov 2020 14:53:58

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered 'No (N)'	Heather Salisbury (b) (4)	12 Nov 2020 14:54:03

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered empty.	Heather Salisbury (b) (4)	12 Nov 2020 14:54:03

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered empty.	Heather Salisbury (b) (4)	12 Nov 2020 14:54:03

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered empty.	System	12 Nov 2020 14:54:03



US3392251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered empty.	Heather Salisbury (b) (4)	12 Nov 2020 14:54:03

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered empty.	Heather Salisbury (b) (4)	12 Nov 2020 14:54:03

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered empty.	Heather Salisbury (b) (4)	12 Nov 2020 14:54:03

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered empty.	Heather Salisbury (b) (4)	12 Nov 2020 14:54:03

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered empty.	System	12 Nov 2020 14:54:03

US3392251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered empty.	(b) (4) Heather Salisbury (b) (4)	12 Nov 2020 14:54:03

US3392251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered empty.	System	12 Nov 2020 14:54:03

US3392251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered empty.	Heather Salisbury (b) (4)	12 Nov 2020 14:54:03



**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered empty.	System	12 Nov 2020 14:54:03

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered empty.	Heather Salisbury (b) (4)	12 Nov 2020 14:54:03

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered empty.	System	12 Nov 2020 14:54:03

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45

US3392251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45

US3392251

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered 'No (N)'	Heather Salisbury (b) (4)	12 Nov 2020 14:54:06

US3392251

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered empty.	Heather Salisbury (b) (4)	12 Nov 2020 14:54:06

US3392251

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	12 Nov 2020 14:54:17



US3392251

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered '12 Nov 2020'	Heather Salisbury (b) (4)	12 Nov 2020 14:54:17

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered '08:50'	Heather Salisbury (b) (4)	12 Nov 2020 14:54:17

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered '12 Nov 2020 08:50'	System	12 Nov 2020 14:54:17

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:28:38
User entered 'Yes (Y)'	(b) (4) Heather Salisbury (b) (4)	12 Nov 2020 14:54:21

**US3392251**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'I'	System	12 Nov 2020 14:54:21

**US3392251**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 64'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-11-12T15:11:08', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '3d7e844a-254f-4c29-b9ce-08ae956dd148'	System	12 Nov 2020 21:11:17
User entered 'No (N)'	System	12 Nov 2020 21:11:17

**US3392251**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Have you been exposed to someone with 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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-11-12T15:11:05', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '3d7e844a-254f-4c29-b9ce-08ae956dd148'	System	12 Nov 2020 21:11:17
User entered 'No (N)'	System	12 Nov 2020 21:11:17



**US3392251**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-11-12T15:11:14', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '3d7e844a-254f-4c29-b9ce-08ae956dd148' User entered '12 Nov 2020 15:11:14'	System	12 Nov 2020 21:11:17
	System	12 Nov 2020 21:11:17

**US3392251**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered '12 Nov 2020 00:01'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered '16 Nov 2020 23:59'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered 'Day 71'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-11-19T07:15:35', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '49fd075f-14d3-4beb-873c-33568d504326'	System	19 Nov 2020 13:16:03
User entered 'No (N)'	System	19 Nov 2020 13:16:03

US3392251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

Have you been exposed to someone with 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 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-11-19T07:15:40', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '49fd075f-14d3-4beb-873c-33568d504326'	System	19 Nov 2020 13:16:03
User entered 'No (N)'	System	19 Nov 2020 13:16:03

**US3392251**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-11-19T07:15:58', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '49fd075f-14d3-4beb-873c-33568d504326' User entered '19 Nov 2020 07:15:58'	System	19 Nov 2020 13:16:03
	System	19 Nov 2020 13:16:03

**US3392251**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered '19 Nov 2020 00:01'	System	12 Sep 2020 17:17:13



**US3392251**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:56:32
Data entry locked.	System	12 Sep 2020 17:17:13
User entered '23 Nov 2020 23:59'	System	12 Sep 2020 17:17:13

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-01T17:13:32', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'd594a05b-b184-4bbe-ae38-f40e08e03904' User entered 'No (N)'	System	01 Dec 2020 23:13:51
	System	01 Dec 2020 23:13:51

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-01T17:13:44', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'd594a05b-b184-4bbe-ae38-f40e08e03904' User entered 'No (N)'	System	01 Dec 2020 23:13:51
	System	01 Dec 2020 23:13:51

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-01T17:13:48', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'd594a05b-b184-4bbe-ae38-f40e08e03904' User entered '01 Dec 2020 17:13:48'	System	01 Dec 2020 23:13:51
	System	01 Dec 2020 23:13:51



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-09T16:27:54', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '427ea2bb-64e8-4d4e-be1e-1dc554abd076' User entered 'No (N)'	System	09 Dec 2020 22:28:13
	System	09 Dec 2020 22:28:13

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-09T16:28:03', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '427ea2bb-64e8-4d4e-be1e-1dc554abd076' User entered 'No (N)'	System	09 Dec 2020 22:28:13
	System	09 Dec 2020 22:28:13

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-09T16:28:10', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '427ea2bb-64e8-4d4e-be1e-1dc554abd076' User entered '09 Dec 2020 16:28:10'	System	09 Dec 2020 22:28:13
	System	09 Dec 2020 22:28:13

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-17T21:34:01', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ffb4c424-191a-4562-979e-f046e6a895c9'	System	18 Dec 2020 03:34:15
User entered 'No (N)'	System	18 Dec 2020 03:34:15

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-17T21:34:07', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ffb4c424-191a-4562-979e-f046e6a895c9'	System	18 Dec 2020 03:34:15
User entered 'No (N)'	System	18 Dec 2020 03:34:15

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-17T21:34:11', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'ffb4c424-191a-4562-979e-f046e6a895c9' User entered '17 Dec 2020 21:34:11'	System	18 Dec 2020 03:34:15
	System	18 Dec 2020 03:34:15

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-23T16:07:14', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'c143d87d-78ce-4742-9069-0b773a626887' User entered 'No (N)'	System	23 Dec 2020 22:07:34



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-23T16:07:26', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'c143d87d-78ce-4742-9069-0b773a626887' User entered 'No (N)'	System	23 Dec 2020 22:07:34

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-23T16:07:30', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'c143d87d-78ce-4742-9069-0b773a626887' User entered '23 Dec 2020 16:07:30'	System	23 Dec 2020 22:07:34
	System	23 Dec 2020 22:07:34

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-28T08:29:44', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '5b47660d-ab99-4748-9ce4-8b142aedef66'	System	28 Dec 2020 14:31:10
User entered 'Yes (Y)'	System	28 Dec 2020 14:31:10

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-28T08:29:52', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '5b47660d-ab99-4748-9ce4-8b142aedef66'	System	28 Dec 2020 14:31:10
User entered 'Yes (Y)'	System	28 Dec 2020 14:31:10

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Please 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-28T08:30:01', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '5b47660d-ab99-4748-9ce4-8b142aedef66'	System	28 Dec 2020 14:31:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Dec 2020 14:31:10



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-28T08:30:12', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '5b47660d-ab99-4748-9ce4-8b142aedef66'	System	28 Dec 2020 14:31:10
User entered 'No (N)'	System	28 Dec 2020 14:31:10

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-28T08:30:24', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '5b47660d-ab99-4748-9ce4-8b142aedef66'	System	28 Dec 2020 14:31:10
User entered 'Yes (Y)'	System	28 Dec 2020 14:31:10

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Please 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-28T08:30:27', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '5b47660d-ab99-4748-9ce4-8b142aedef66'	System	28 Dec 2020 14:31:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Dec 2020 14:31:10

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2020-12-28T08:31:01', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '5b47660d-ab99-4748-9ce4-8b142aedef66' User entered '28 Dec 2020 08:31:01'	System	28 Dec 2020 14:31:10
	System	28 Dec 2020 14:31:10

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-01-07T11:08:04', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b2d5e0c5-7b15-4f70-b7f0-c95c75ef2c71' User entered 'No (N)'	System	07 Jan 2021 17:08:15
	System	07 Jan 2021 17:08:15



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-01-07T11:08:06', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b2d5e0c5-7b15-4f70-b7f0-c95c75ef2c71'	System	07 Jan 2021 17:08:15
User entered 'No (N)'	System	07 Jan 2021 17:08:15

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-01-07T11:08:10', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b2d5e0c5-7b15-4f70-b7f0-c95c75ef2c71' User entered '07 Jan 2021 11:08:10'	System	07 Jan 2021 17:08:15
	System	07 Jan 2021 17:08:15

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-01-11T17:47:42', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b6de590b-97b2-457f-97a7-f50a8511f3df'	System	11 Jan 2021 23:47:59
User entered 'No (N)'	System	11 Jan 2021 23:47:59

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-01-11T17:47:50', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b6de590b-97b2-457f-97a7-f50a8511f3df'	System	11 Jan 2021 23:47:59
User entered 'No (N)'	System	11 Jan 2021 23:47:59

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-01-11T17:47:56', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'b6de590b-97b2-457f-97a7-f50a8511f3df'	System	11 Jan 2021 23:47:59
User entered '11 Jan 2021 17:47:56'	System	11 Jan 2021 23:47:59



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-01-21T16:28:29', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '25c145bd-5b8a-4e61-99a4-647f6dd08e0f' User entered 'No (N)'	System	21 Jan 2021 22:29:07
	System	21 Jan 2021 22:29:07

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-01-21T16:28:43', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '25c145bd-5b8a-4e61-99a4-647f6dd08e0f' User entered 'No (N)'	System	21 Jan 2021 22:29:07

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-01-21T16:29:04', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '25c145bd-5b8a-4e61-99a4-647f6dd08e0f' User entered '21 Jan 2021 16:29:04'	System	21 Jan 2021 22:29:07
	System	21 Jan 2021 22:29:07

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-01-25T15:33:41', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'fa51346e-b819-43ed-9dac-50fd8d0cf786'	System	25 Jan 2021 21:33:52
User entered 'No (N)'	System	25 Jan 2021 21:33:52

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-01-25T15:33:46', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'fa51346e-b819-43ed-9dac-50fd8d0cf786'	System	25 Jan 2021 21:33:52
User entered 'No (N)'	System	25 Jan 2021 21:33:52

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-01-25T15:33:50', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'fa51346e-b819-43ed-9dac-50fd8d0cf786'	System	25 Jan 2021 21:33:52
User entered '25 Jan 2021 15:33:50'	System	25 Jan 2021 21:33:52

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-02T08:04:33', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '1b4dd764-c258-4f04-b398-39b7ceb09174' User entered 'No (N)'	System	02 Feb 2021 14:04:44
	System	02 Feb 2021 14:04:44



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-02T08:04:36', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '1b4dd764-c258-4f04-b398-39b7ceb09174'	System	02 Feb 2021 14:04:44
User entered 'No (N)'	System	02 Feb 2021 14:04:44

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-02T08:04:41', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '1b4dd764-c258-4f04-b398-39b7ceb09174' User entered '02 Feb 2021 08:04:41'	System	02 Feb 2021 14:04:44
	System	02 Feb 2021 14:04:44

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-11T07:50:18', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '6f6ac75f-8c15-45e5-b78e-eff178438def' User entered 'No (N)'	System	11 Feb 2021 13:50:30
	System	11 Feb 2021 13:50:30

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-11T07:50:23', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '6f6ac75f-8c15-45e5-b78e-eff178438def' User entered 'No (N)'	System	11 Feb 2021 13:50:30

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-11T07:50:27', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '6f6ac75f-8c15-45e5-b78e-eff178438def' User entered '11 Feb 2021 07:50:27'	System	11 Feb 2021 13:50:30
	System	11 Feb 2021 13:50:30



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-17T12:00:45', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '09d4e180-2ef9-46d2-a28a-836962f61e3a' User entered 'No (N)'	System	17 Feb 2021 18:02:47
	System	17 Feb 2021 18:02:47

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-17T12:00:48', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '09d4e180-2ef9-46d2-a28a-836962f61e3a' User entered 'No (N)'	System	17 Feb 2021 18:02:47
	System	17 Feb 2021 18:02:47

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-17T12:00:51', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '09d4e180-2ef9-46d2-a28a-836962f61e3a' User entered '17 Feb 2021 12:00:51'	System	17 Feb 2021 18:02:47
	System	17 Feb 2021 18:02:47

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-22T07:36:30', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '621c83a8-5915-47a0-a20a-20d4dbb6c84a' User entered 'No (N)'	System	22 Feb 2021 13:36:51
	System	22 Feb 2021 13:36:51

US3392251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:30

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-22T07:36:33', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '621c83a8-5915-47a0-a20a-20d4dbb6c84a' User entered 'No (N)'	System	22 Feb 2021 13:36:51
	System	22 Feb 2021 13:36:51

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-22T07:36:37', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '621c83a8-5915-47a0-a20a-20d4dbb6c84a' User entered '22 Feb 2021 07:36:37'	System	22 Feb 2021 13:36:51
	System	22 Feb 2021 13:36:51

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-03-04T19:38:44-06:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'baa23371-94f8-428d-8b35-6c7f0f9d92b8'	System	05 Mar 2021 01:38:56
User entered 'No (N)'	System	05 Mar 2021 01:38:56



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-03-04T19:38:47-06:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'baa23371-94f8-428d-8b35-6c7f0f9d92b8'	System	05 Mar 2021 01:38:56
User entered 'No (N)'	System	05 Mar 2021 01:38:56

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-03-04T19:38:51-06:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'baa23371-94f8-428d-8b35-6c7f0f9d92b8' User entered '04 Mar 2021 19:38:51'	System	05 Mar 2021 01:38:56
	System	05 Mar 2021 01:38:56

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-03-10T08:00:34-06:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'fbe2d030-2ec1-411f-b9ec-22f3dbbd4121'	System	10 Mar 2021 14:00:45
User entered 'No (N)'	System	10 Mar 2021 14:00:45

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-03-10T08:00:36-06:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'fbe2d030-2ec1-411f-b9ec-22f3dbbd4121'	System	10 Mar 2021 14:00:45
User entered 'No (N)'	System	10 Mar 2021 14:00:45

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-03-10T08:00:39-06:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'fbe2d030-2ec1-411f-b9ec-22f3dbbd4121' User entered '10 Mar 2021 08:00:39'	System	10 Mar 2021 14:00:45
	System	10 Mar 2021 14:00:45



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-03-22T15:37:25-05:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'afa7d736-07e3-46f1-9931-39f28def9b24'	System	22 Mar 2021 20:37:33
User entered 'No (N)'	System	22 Mar 2021 20:37:33

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-03-22T15:37:27-05:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'afa7d736-07e3-46f1-9931-39f28def9b24'	System	22 Mar 2021 20:37:33
User entered 'No (N)'	System	22 Mar 2021 20:37:33



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-03-22T15:37:30-05:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'afa7d736-07e3-46f1-9931-39f28def9b24'	System	22 Mar 2021 20:37:33
User entered '22 Mar 2021 15:37:30'	System	22 Mar 2021 20:37:33

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-03-31T12:04:43-05:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e30e399d-451d-4baf-9e6b-28953e93a4fe'	System	31 Mar 2021 17:10:22
User entered 'No (N)'	System	31 Mar 2021 17:10:22

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-03-31T12:04:45-05:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e30e399d-451d-4baf-9e6b-28953e93a4fe'	System	31 Mar 2021 17:10:22
User entered 'No (N)'	System	31 Mar 2021 17:10:22

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-03-31T12:04:48-05:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: 'e30e399d-451d-4baf-9e6b-28953e93a4fe' User entered '31 Mar 2021 12:04:48'	System	31 Mar 2021 17:10:22
	System	31 Mar 2021 17:10:22

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-04-07T10:46:26-05:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0a1164a2-b2a1-43a5-acd9-e84835372fe8' User entered 'No (N)'	System	07 Apr 2021 15:46:43

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-04-07T10:46:33-05:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0a1164a2-b2a1-43a5-acd9-e84835372fe8' User entered 'No (N)'	System	07 Apr 2021 15:46:43

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-04-07T10:46:37-05:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '0a1164a2-b2a1-43a5-acd9-e84835372fe8' User entered '07 Apr 2021 10:46:37'	System	07 Apr 2021 15:46:43
	System	07 Apr 2021 15:46:43

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-09T07:34:10', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4dbef991-2fad-41fa-a361-5041c49345fb' User entered 'No (N)'	System	09 Feb 2021 13:34:27
	System	09 Feb 2021 13:34:27

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

Have you been exposed to someone with 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 (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-09T07:34:14', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4dbef991-2fad-41fa-a361-5041c49345fb' User entered 'No (N)'	System	09 Feb 2021 13:34:27

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-02-09T07:34:24', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '4dbef991-2fad-41fa-a361-5041c49345fb' User entered '09 Feb 2021 07:34:24'	System	09 Feb 2021 13:34:27
	System	09 Feb 2021 13:34:27



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '31 Oct 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '04 Nov 2022 23:59'	System	20 Nov 2020 08:02:49



**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '07 Nov 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '11 Nov 2022 23:59'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '14 Nov 2022 00:01'	System	20 Nov 2020 08:02:49

**US3392251**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:28:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:02:49
Amendment Manager: User entered '18 Nov 2022 23:59'	System	20 Nov 2020 08:02:49

US3392251

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:28:30**

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 07:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-03-04T19:39:14-06:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '3bd75ef2-82ae-46e8-8438-dda05271bf33'	System	05 Mar 2021 01:39:31
User entered 'No (N)'	System	05 Mar 2021 01:39:31

**US3392251**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5E7BADDD-4B3D-4F95-807A-82138CF0A387)', Time: '2021-03-04T19:39:23-06:00', User OID: 'PatientReportedOutcome (US3392251)', ODM File OID: '3bd75ef2-82ae-46e8-8438-dda05271bf33'	System	05 Mar 2021 01:39:31
User entered '04 Mar 2021 19:39:23'	System	05 Mar 2021 01:39:31



**US3392251**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 23:03:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:54:59

US3392251

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 23:03:00
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:54:59

**US3392251**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 23:03:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:54:59

**US3392251**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 23:03:00
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:54:59

US3392251

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 23:03:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:55:03

**US3392251**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:40:45
User entered 'I'	System	08 Jan 2021 20:55:03

**US3392251**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 20:55:14

**US3392251**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered '23 Dec 2020'	(b) (4), (b) (6)	08 Jan 2021 20:55:14



**US3392251**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Jan 2021 20:55:14

**US3392251**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 20:55:14

**US3392251**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:15
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 20:55:18

**US3392251**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:15
User entered 'I'	System	08 Jan 2021 20:55:18

**US3392251**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:26
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 22:17:52

US3392251

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:26
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	03 Feb 2021 22:27:48
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	03 Feb 2021 22:27:48
User entered '3 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 22:27:48
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	03 Feb 2021 22:19:36
User entered '20 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 22:19:36
User entered '3 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 22:17:52

US3392251

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:26
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Feb 2021 22:17:52

US3392251

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:26
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 22:17:52



US3392251

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:26
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 22:17:57

**US3392251**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:26
User entered 'I'	System	03 Feb 2021 22:17:57

**US3392251**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:28:55

US3392251

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24MAR2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same sample data is not entered in EDC. Please review and update the sample data in EDC under Immunogenicity eCRF under Visit 04 folder as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:20:05
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24MAR2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same sample data is not entered in EDC. Please review and update the sample data in EDC under Immunogenicity eCRF under Visit 04 folder as appropriate. Else Clarify, Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 15:15:11
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24MAR2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same sample data is not entered in EDC. Please review and update the sample data in EDC under Immunogenicity eCRF under Visit 04 folder as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:31:46
User entered '4 Mar 2021'	(b) (4), (b) (6)	04 Mar 2021 18:28:55

**US3392251**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:28:55

**US3392251**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:28:55

US3392251

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:30:20

**US3392251**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:38
User entered 'I'	System	04 Mar 2021 18:30:20



US3392251

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:12:37

US3392251

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:12:37

**US3392251**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:12:37

**US3392251**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User entered 'VISIT4'	System	15 Apr 2021 15:12:37

US3392251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:12:58

US3392251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:12:58

**US3392251**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:12:58

**US3392251**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User entered empty.	System	15 Apr 2021 15:12:58



US3392251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:12:58

US3392251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:12:58

**US3392251**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:12:58

**US3392251**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:12:58

**US3392251**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User entered empty.	System	15 Apr 2021 15:12:58

US3392251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:12:58

US3392251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User entered empty.	System	15 Apr 2021 15:12:58

US3392251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:12:58



**US3392251**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User entered empty.	System	15 Apr 2021 15:12:58

US3392251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:12:58

US3392251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User entered empty.	System	15 Apr 2021 15:12:58

US3392251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18

**US3392251**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18

US3392251

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:13:05

US3392251

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:13:05

US3392251

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:13:23



US3392251

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:13:23

**US3392251**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '08:35'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:13:23

**US3392251**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User entered '24 Mar 2021 08:35'	System	15 Apr 2021 15:13:23

US3392251

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:13:53

**US3392251**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:18
User entered 'I'	System	15 Apr 2021 15:13:53

US3392251

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

Form: Visit Date

Generated On: 09 Jun 2021 17:28:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:00:18

**US3392251**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:00:18

**US3392251**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:00:18



**US3392251**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered 'UNBLND_DECIDE'	System	16 Jan 2021 01:00:18

**US3392251**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:28:30**

**Date of updated informed consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:00:51

**US3392251**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:28:30**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '0'	(b) (4) Brandon Illickal (b) (4)	08 Mar 2021 23:38:32
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:57:20

**US3392251**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:28:30**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:00:51

**US3392251**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:28:30**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Brandon Illickal (b) (4)	08 Mar 2021 23:38:32
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:57:20

US3392251

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:30

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:00:51

US3392251

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:30

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:00:51

**US3392251**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:28:30**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 04:40:24
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	16 Jan 2021 01:00:51



US3392251

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:30

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 04:40:24
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	16 Jan 2021 01:00:51

**US3392251**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:28:30**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:00:51

**US3392251**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:28:30**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered '1'	System	16 Jan 2021 01:00:51

**US3392251**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered 'I'	System	16 Jan 2021 01:00:51

US3392251

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '63.0' in	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '210.0' lb	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered '37.27761'	System	16 Jan 2021 01:08:35
DataPoint set to visible.	System	16 Jan 2021 01:00:51

US3392251

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '63.0' in	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:08:35



US3392251

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '210.0' lb	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered '37.27761'	System	16 Jan 2021 01:08:35
DataPoint set to visible.	System	16 Jan 2021 01:00:51

US3392251

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
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	16 Jan 2021 01:09:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Jan 2021 01:09:28
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Jan 2021 01:08:35
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:09:13
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '15:27' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:09:13
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered '14 Jan 2021 15:27'	System	16 Jan 2021 01:09:13
User entered empty.	System	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '98.6' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:09:13
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35



US3392251

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:09:13
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

**US3392251**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:08:35

**US3392251**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '79' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:09:13
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered 'bpm'	System	16 Jan 2021 01:09:13
User entered empty.	System	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '14' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:09:13
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

**US3392251**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered 'breaths/min'	System	16 Jan 2021 01:09:13
User entered empty.	System	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '111' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:09:13
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

**US3392251**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered 'mmHg'	System	16 Jan 2021 01:09:13
User entered empty.	System	16 Jan 2021 01:08:35



US3392251

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '75' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:09:13
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered 'mmHg'	System	16 Jan 2021 01:09:13
User entered empty.	System	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '63.0' in	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:08:35

**US3392251**

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

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:28:30**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '210.0' lb	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered '37.27761'	System	16 Jan 2021 01:08:35
DataPoint set to visible.	System	16 Jan 2021 01:00:51

**US3392251**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
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	16 Jan 2021 01:10:15
User entered 'Yes (Y)' reason for change: Data Entry Error	System	16 Jan 2021 01:10:15
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Jan 2021 01:08:35
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:10:15
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35



US3392251

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '16:47' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:10:15
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered '14 Jan 2021 16:47'	System	16 Jan 2021 01:10:15
User entered empty.	System	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '98.6' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:10:15
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:10:15
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

**US3392251**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '77' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:10:15
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

**US3392251**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered 'bpm'	System	16 Jan 2021 01:10:15
User entered empty.	System	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '14' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:10:15
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35



US3392251

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered 'breaths/min'	System	16 Jan 2021 01:10:15
User entered empty.	System	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '110' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:10:15
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered 'mmHg'	System	16 Jan 2021 01:10:15
User entered empty.	System	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '76' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:10:15
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 01:08:35

US3392251

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered 'mmHg'	System	16 Jan 2021 01:10:15
User entered empty.	System	16 Jan 2021 01:08:35

US3392251

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:06:23

US3392251

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:06:23

US3392251

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:07:11



US3392251

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:07:11

US3392251

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

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)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:07:11

**US3392251**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 17:28:30**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered 'mRNA-1273'	System	16 Jan 2021 01:07:11
DataPoint set to visible.	System	16 Jan 2021 01:00:51

US3392251

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:07:11

US3392251

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '16:15'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:07:11

**US3392251**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered '14 Jan 2021 16:15'	System	16 Jan 2021 01:07:11

US3392251

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:07:11

US3392251

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

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered 'ONCE'	System	16 Jan 2021 01:07:11



**US3392251**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered 'INTRAMUSCULAR'	System	16 Jan 2021 01:07:11

**US3392251**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:28:30**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:07:51

**US3392251**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:28:30**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:07:51

**US3392251**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '15:47'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:07:51

**US3392251**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered '14 Jan 2021 15:47'	System	16 Jan 2021 01:07:51

US3392251

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:28:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:08:06

**US3392251**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:28:30**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:08:06

**US3392251**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '15:49'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:08:06



**US3392251**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered '14 Jan 2021 15:49'	System	16 Jan 2021 01:08:06

US3392251

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

Form: Continuing

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Jan 2021 01:08:12

**US3392251**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:40
User entered 'I'	System	16 Jan 2021 01:08:12

US3392251

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:45:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Mar 2021 20:46:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 20:46:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 20:46:02
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 22:31:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 22:31:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 00:24:09

US3392251

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:45:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 12:30:29
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Data added' (Site from System).	(b) (4), (b) (6)	29 Mar 2021 20:46:19
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Mar 2021 20:46:02
User entered '3 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 20:46:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 22:31:10
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 00:24:09

US3392251

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:45:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 22:31:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Jan 2021 00:24:09

**US3392251**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:45:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 00:24:09

US3392251

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:45:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
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	04 Feb 2021 02:01:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	04 Feb 2021 02:01:34
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 22:31:20
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 22:31:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 00:24:13



**US3392251**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:45:27
User entered '1'	System	04 Feb 2021 02:01:34
User entered empty.	System	03 Feb 2021 22:31:20
User entered '1'	System	22 Jan 2021 00:24:13

**US3392251**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:45:27
User entered '1'	System	04 Feb 2021 02:01:34
User entered empty.	System	03 Feb 2021 22:31:20
User entered '1'	System	22 Jan 2021 00:24:13
DataPoint set to visible.	System	22 Jan 2021 00:24:13

**US3392251**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:26:05

**US3392251**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:26:05

**US3392251**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:26:05

**US3392251**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered 'OLD29'	System	08 Feb 2021 20:26:05

US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Feb 2021 20:27:10

US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10



US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '13:21'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered '8 Feb 2021 13:21'	System	08 Feb 2021 20:27:10

US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '79'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered 'bpm'	System	08 Feb 2021 20:27:10



US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered 'breaths/min'	System	08 Feb 2021 20:27:10

US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '122'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered 'mmHg'	System	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '74'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered 'mmHg'	System	08 Feb 2021 20:27:10

US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10



US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '14:09'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered '8 Feb 2021 14:09'	System	08 Feb 2021 20:27:10

US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '82'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered 'bpm'	System	08 Feb 2021 20:27:10



**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

US3392251

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered 'breaths/min'	System	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '121'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered 'mmHg'	System	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '79'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered 'mmHg'	System	08 Feb 2021 20:27:10

**US3392251**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:28:30**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:14

**US3392251**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:28:30**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 20:27:14



US3392251

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:38

US3392251

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:38

US3392251

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

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)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:38

**US3392251**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:28:30**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered 'mRNA-1273'	System	08 Feb 2021 20:27:38
DataPoint set to visible.	System	04 Feb 2021 02:01:34

US3392251

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:38

US3392251

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '13:38'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:38

**US3392251**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered '8 Feb 2021 13:38'	System	08 Feb 2021 20:27:38

US3392251

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:38



US3392251

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered 'ONCE'	System	08 Feb 2021 20:27:38

US3392251

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 20:27:38

**US3392251**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:27:43

**US3392251**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:43
User entered '1'	System	08 Feb 2021 20:27:43

**US3392251**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 00:33:14

**US3392251**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 00:33:14

**US3392251**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 00:33:14

**US3392251**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:28:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 00:33:14



**US3392251**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 00:33:18

**US3392251**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:28:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:41
User entered 'I'	System	18 Feb 2021 00:33:18

US3392251

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4)	08 Mar 2021 23:39:44

**US3392251**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '05 Mar 2021'	(b) (4)	08 Mar 2021 23:39:44

**US3392251**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Clinic (Clinic)'	(b) (4) Brandon Illickal (b) (4)	08 Mar 2021 23:39:44

**US3392251**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:28:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User entered 'OLD57'	System	08 Mar 2021 23:39:44

US3392251

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'No (N)'	(b) (4)	08 Mar 2021 23:39:51

US3392251

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4)	08 Mar 2021 23:39:51



**US3392251**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4)	08 Mar 2021 23:39:51

**US3392251**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User entered empty.	System	08 Mar 2021 23:39:51

US3392251

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4)	08 Mar 2021 23:39:51

US3392251

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4)	08 Mar 2021 23:39:51

**US3392251**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4)	08 Mar 2021 23:39:51

**US3392251**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4)	08 Mar 2021 23:39:51

**US3392251**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User entered empty.	System	08 Mar 2021 23:39:51

US3392251

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4)	08 Mar 2021 23:39:51



**US3392251**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User entered empty.	System	08 Mar 2021 23:39:51

US3392251

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4)	08 Mar 2021 23:39:51

**US3392251**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User entered empty.	System	08 Mar 2021 23:39:51

US3392251

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4)	08 Mar 2021 23:39:51

**US3392251**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User entered empty.	System	08 Mar 2021 23:39:51

**US3392251**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04

**US3392251**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:28:30**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04

US3392251

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'No (N)'	(b) (4)	08 Mar 2021 23:39:54



**US3392251**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:28:30**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered empty.	(b) (4)	08 Mar 2021 23:39:54

US3392251

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Yes (Y)'	(b) (4)	08 Mar 2021 23:40:12

US3392251

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '05 Mar 2021'	(b) (4)	08 Mar 2021 23:40:12
	Brandon Illickal (b) (4)	

**US3392251**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered '13:58'	(b) (4) Brandon Illickal (b) (4)	08 Mar 2021 23:40:12

**US3392251**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:36:04
User entered '05 Mar 2021 13:58'	System	08 Mar 2021 23:40:12

US3392251

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:28:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:31:44
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:09
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	21 Oct 2020 18:52:42

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:09:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:19:58
User entered	System	22 Oct 2020 16:19:51
'USA-US119-2020-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	22 Oct 2020 16:19:51

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:00:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:00:45
Data point term sent to Coder	System	21 Oct 2020 19:00:07
User entered 'pneumonia'	Brandon Illickal (b) (4) (b) (4) (b) (4)	21 Oct 2020 18:59:07



**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'No (N)'	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'No (N)'	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '20 Oct 2020'	Brandon Illickal (b) (4)  	21 Oct 2020 18:59:07

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered empty.	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:59:07

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	11 Dec 2020 17:18:54
User entered 'No (N)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	11 Dec 2020 17:18:54
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	11 Dec 2020 17:18:05
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:09:37
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) (6)	11 Dec 2020 19:52:58
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 'updated; still waiting for medical records' (Site from Safety).	Brandon Illickal (b) (4)	11 Dec 2020 17:19:12
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Dec 2020 17:18:40
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	11 Dec 2020 17:18:40
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	11 Dec 2020 17:18:05
User entered '22 Oct 2020' reason for change: New Information	Brandon Illickal (b) (4)	11 Dec 2020 17:18:05
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)	30 Oct 2020 20:36:22
User entered empty.	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07



US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered empty.	Brandon Illickal (b) (4)  	21 Oct 2020 18:59:07

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:59:07

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'Grade 4 (Grade 4)'	Brandon Illickal (b) (4)  	21 Oct 2020 18:59:07

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'Yes (Y)'	Brandon Illickal (b) (4)  	21 Oct 2020 18:59:07

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '0'	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '0'	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
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) (6)	22 Oct 2020 20:52:53
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 hospitalized' (Site from System).	Brandon Illickal (b) (4)	21 Oct 2020 18:59:42
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	21 Oct 2020 18:59:07
User entered 'I'	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '20 Oct 2020'	Brandon Illickal (b) (4)  	21 Oct 2020 18:59:07



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:09:37
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 19:53:10
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated; still waiting for medical records' (Site from Safety).	Brandon Illickal (b) (4)	11 Dec 2020 17:19:17
User entered '22 Oct 2020' reason for change: New Information	Brandon Illickal (b) (4)	11 Dec 2020 17:18:05
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:36:13
User entered empty.	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'No (N)'	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered empty.	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '0'	Brandon Illickal (b) (4)  	21 Oct 2020 18:59:07

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '0'	Brandon Illickal (b) (4)  	21 Oct 2020 18:59:07

US3392251

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '0'	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)  	21 Oct 2020 18:59:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)  	21 Oct 2020 18:59:07



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 19:40:37
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' answered with 'updated' (Site from Safety).	Brandon Illickal (b) (4)	25 Nov 2020 18:30:32
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	25 Nov 2020 18:02:13
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:37:16
User entered 'None (NONE)'	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected as the subject was hospitalized for this AE. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:19:03
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected as the subject was hospitalized for this AE. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' answered with 'NO RECORDS ON FILE OF MEDICATION OR PROCEDURE.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 21:41:19
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected as the subject was hospitalized for this AE. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 14:03:00
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	21 Oct 2020 19:00:00
User entered '1' reason for change: Data Entry Error	Brandon Illickal (b) (4)	21 Oct 2020 19:00:00
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	21 Oct 2020 18:59:07
User entered '0'	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '0'	Brandon Illickal (b) (4)  	21 Oct 2020 18:59:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '0'	Brandon Illickal (b) (4)  	21 Oct 2020 18:59:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 19:53:15
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated; still waiting for medical records' (Site from Safety).	Brandon Illickal (b) (4)	11 Dec 2020 17:19:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Brandon Illickal (b) (4)	11 Dec 2020 17:18:40
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Brandon Illickal (b) (4)	11 Dec 2020 17:18:05
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:36:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered empty.	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User closed query 'Per DM CLR: SAE Narrative = CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 15:44:19
Query 'Per DM CLR: SAE Narrative = CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	11 Feb 2021 07:35:14
User opened query 'Per DM CLR: SAE Narrative = CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 00:05:48
User closed query 'PV Query: Please provide the dates for the laboratory tests provided in the ecrf (covid testing x 2 and chest xray).' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:31:41
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) (6)	07 Jan 2021 15:31:38
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:31:34
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:31:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that subject had "OXYGEN". However, this is not recorded in the Concomitant Medication eCRF. Please review and recorded this in its respective eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:19:32
Query 'Per DM CLR: Narrative indicates that subject had "OXYGEN". However, this is not recorded in the Concomitant Medication eCRF. Please review and recorded this in its respective eCRF. Otherwise, clarify.' answered with 'NO RECORDS ON FILE OF MEDICATION OR PROCEDURE.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 21:42:05
Query 'PV Query: Please provide the dates for the laboratory tests provided in the ecrf (covid testing x 2 and chest xray).' answered with 'NO RECORDS ON FILE OF MEDICATION OR PROCEDURE.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 21:41:42
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 RECORDS ON FILE OF MEDICATION OR PROCEDURE.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 21:41:37
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'NO RECORDS ON FILE OF MEDICATION OR PROCEDURE.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 21:41:31
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'NO RECORDS ON FILE OF MEDICATION OR PROCEDURE.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 21:41:26



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that subject had "OXYGEN". However, this is not recorded in the Concomitant Medication eCRF. Please review and recorded this in its respective eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 14:03:08
User opened query 'PV Query: Please provide the dates for the laboratory tests provided in the ecrf (covid testing x 2 and chest xray).' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 21:21:31
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)	04 Dec 2020 21:21:15
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) (6)	30 Nov 2020 19:41:00
User closed query 'PV Query: Please provide the dates for the laboratory tests provided in the ecrf (covid testing x 2 and chest xray).' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 19:40:54
Query 'PV Query: Please provide the dates for the laboratory tests provided in the ecrf (covid testing x 2 and chest xray).' answered with 'hospital records have been requested. Data will be entered when records are received.' (Site from Safety).	Brandon Illickal (b) (4)	25 Nov 2020 18:30:56
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 'hospital records have been requested. Data will be entered when records are received.' (Site from Safety).	Brandon Illickal (b) (4)	25 Nov 2020 18:30:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:30

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the dates for the laboratory tests provided in the ecrf (covid testing x 2 and chest xray).' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:37:02
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)	30 Oct 2020 20:36:54
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:36:32
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:36:01
User entered 'Patient presented to ER c/o cough/sob,fever, body aches, fatigue. Abrupt onset;progressive. Hypoxic/ Oxygen - requiring in ER. Admitted to non-ICU bed. Covid 19 testing ( PCR ) x 2 NEG by attending hospitalist report. CXR c/w pneumonia.'	Brandon Illickal (b) (4)	21 Oct 2020 18:59:07

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 18:59:07

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 18:59:07

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 18:59:07

US3392251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'USA-US119-2020-mRNA-1273-P301000012'	System	29 Dec 2020 15:07:59
User entered 'New'	(b) (4), (b) (6)	29 Dec 2020 15:07:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM). Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'subject did not come in for illness visit' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:55:33
DataPoint Verified.	Brandon Illickal (b) (4)	21 Apr 2021 18:38:50
User closed query 'PV Query: Please consider updating event term to final diagnosis. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 15:09:37
Query 'PV Query: Please consider updating event term to final diagnosis. Please leave query open until information is available.' answered with 'Final is fever' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 13:53:58
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 21:03:06
User opened query 'PV Query: Please consider updating event term to final diagnosis. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 10:59:31
User closed query 'PV Query: Please provide temperature and date of fever.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 14:18:36
	(b) (4), (b) (6)	07 Jan 2021 15:31:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider updating event term to final diagnosis.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:31:52
Query 'PV Query: Please consider updating event term to final diagnosis.' answered with '(SITE HAS NOT RECEIVED MEDICAL RECORDS RELATED TO THE SADVERSE EVENT TO THIS CURRENT DATE & TIME).SITE IS WAITING TO RECEIVE MEDICAL RECORDS RELATED TO THE ADVERSE EVENT.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 23:05:35
Query 'PV Query: Please provide temperature and date of fever.' answered with '(SITE HAS NOT RECEIVED MEDICAL RECORDS RELATED TO THE SADVERSE EVENT TO THIS CURRENT DATE & TIME).SITE IS WAITING TO RECEIVE MEDICAL RECORDS RELATED TO THE ADVERSE EVENT.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 23:05:31
User opened query 'PV Query: Please provide temperature and date of fever.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:28:23
User opened query 'PV Query: Please consider updating event term to final diagnosis.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:28:07
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Dec 2020 17:41:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Dec 2020 17:41:21
Data point term sent to Coder	System	28 Dec 2020 17:40:41
User entered 'fever'	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User closed query 'Per CDM: Please confirm if this AE is a solicited adverse reaction based on information provided on pg 32 of CCGs. Thank you ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:20:13
Query 'Per CDM: Please confirm if this AE is a solicited adverse reaction based on information provided on pg 32 of CCGs. Thank you ' answered with 'THE AE IS NOT A SOLICITED ADVERSE REACTION.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 23:00:45
User opened query 'Per CDM: Please confirm if this AE is a solicited adverse reaction based on information provided on pg 32 of CCGs. Thank you ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 13:52:27
User entered 'No (N)'	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'No (N)'	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '25 Dec 2020'	Brandon Illickal (b) (4)  	28 Dec 2020 17:40:37

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:28:30**

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered empty.	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:28:30**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 17:40:37

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'No (N)'	Brandon Illickal (b) (4)  	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '28 Dec 2020'	Brandon Illickal (b) (4)  	28 Dec 2020 17:40:37



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered empty.	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:28:30**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 17:40:37

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'Grade 3/Severe (Grade 3/Severe)'	Brandon Illickal (b) (4)  	28 Dec 2020 17:40:37

US3392251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
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	28 Dec 2020 17:40:57
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	28 Dec 2020 17:40:37
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '0'	Brandon Illickal (b) (4)  	28 Dec 2020 17:40:37

US3392251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '0'	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

US3392251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
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).		28 Dec 2020 17:40:57
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).		28 Dec 2020 17:40:57
User entered '1' reason for change: Data Entry Error	Brandon Illickal (b) (4)	28 Dec 2020 17:40:57
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	28 Dec 2020 17:40:37
User entered '0'	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '25 Dec 2020'	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '28 Dec 2020'	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'No (N)'	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered empty.	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '0'	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '0'	Brandon Illickal (b) (4)  	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '0'	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)  	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)  	28 Dec 2020 17:40:37



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'Not Applicable (NOT APPLICABLE)'	Brandon Illickal (b) (4)  	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '0'	Brandon Illickal (b) (4)  	28 Dec 2020 17:40:37

US3392251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please enter data when it becomes available. This query will remain open in the meantime. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 03:04:22
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 03:03:42
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'records are being requested from patient; ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 14:12:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:09:37
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 12:04:02
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:32:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with '(SITE HAS NOT RECEIVED MEDICAL RECORDS RELATED TO THE SADVERSE EVENT TO THIS CURRENT DATE & TIME).SITE IS WAITING TO RECEIVE MEDICAL RECORDS RELATED TO THE ADVERSE EVENT.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 23:05:10
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:27:32
User entered 'I'	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered '0'	Brandon Illickal (b) (4)  	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brandon Illickal (b) (4)  	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:09:37
User entered empty.	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide temperature and date of fever. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 21:27:33
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 21:27:25
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 21:27:18
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 21:27:11
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 21:27:01
User closed query 'PV Query: Please provide temperature and date of fever. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 13:57:27



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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:28:30

[Narrative](#)

Audit	User	Time (GMT)
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 13:57:24
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 13:57:20
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 13:57:16
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 13:57:09
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
Query 'PV Query: Please provide temperature and date of fever. Please leave query open until information is available.' answered with 'Awaiting medical records; patient is having trouble obtaining them currently' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 14:12:31

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
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. Please leave query open until information is available.' answered with 'Awaiting medical records; patient is having trouble obtaining them currently' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:11:45
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. Please leave query open until information is available.' answered with 'Awaiting medical records; patient is having trouble obtaining them currently' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:10:42
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. Please leave query open until information is available.' answered with 'Awaiting medical records; patient is having trouble obtaining them currently' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:10:03
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' answered with 'Awaiting medical records; patient is having trouble obtaining them currently' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:07:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:09:37
User opened query 'PV Query: Please provide temperature and date of fever. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 14:18:49

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Folder: Adverse Events

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[Narrative](#)

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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 14:18:20
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 14:17:50
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 14:17:36
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 14:17:16
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:32:21
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)	07 Jan 2021 15:32:16

US3392251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Narrative](#)

Audit	User	Time (GMT)
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) (6)	07 Jan 2021 15:32:13
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with '(SITE HAS NOT RECEIVED MEDICAL RECORDS RELATED TO THE SADVERSE EVENT TO THIS CURRENT DATE & TIME).SITE IS WAITING TO RECEIVE MEDICAL RECORDS RELATED TO THE ADVERSE EVENT.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 23:05:24
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 '(SITE HAS NOT RECEIVED MEDICAL RECORDS RELATED TO THE SADVERSE EVENT TO THIS CURRENT DATE & TIME).SITE IS WAITING TO RECEIVE MEDICAL RECORDS RELATED TO THE ADVERSE EVENT.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 23:05:18
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 '(SITE HAS NOT RECEIVED MEDICAL RECORDS RELATED TO THE SADVERSE EVENT TO THIS CURRENT DATE & TIME).SITE IS WAITING TO RECEIVE MEDICAL RECORDS RELATED TO THE ADVERSE EVENT.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 23:05:14

US3392251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:30

[Narrative](#)

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.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:27:55
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 Jan 2021 15:27:47
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 Jan 2021 15:27:39
User entered 'patient was admitted to hospital with fever. awaiting medical records and will update when received.'	Brandon Illickal (b) (4)	28 Dec 2020 17:40:37

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 17:40:37

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 17:40:37

**US3392251**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Dec 2020 17:40:37



US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:28:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:31:44
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User closed query 'Per ETRTR: According to SAE "Fever" CRF, medication was provided, but no medication related to "Fever" SAE has been found within this folder. Please add Medication(s) dosed or consider reconciling data within SAE CRF page, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:35:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 20:55:24
Query 'Per ETRTR: According to SAE "Fever" CRF, medication was provided, but no medication related to "Fever" SAE has been found within this folder. Please add Medication(s) dosed or consider reconciling data within SAE CRF page, thanks.' answered with 'No con med taken' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 20:53:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 20:52:46
User opened query 'Per ETRTR: According to SAE "Fever" CRF, medication was provided, but no medication related to "Fever" SAE has been found within this folder. Please add Medication(s) dosed or consider reconciling data within SAE CRF page, thanks.' (Site from CRA).	(b) (4), (b) (6)	18 Jan 2021 16:34:05
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	14 Jan 2021 23:58:29

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Jan 2021 00:00:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 00:00:59
Data point term sent to Coder	System	14 Jan 2021 23:59:45
User entered 'Metformin'	Brandon Illickal (b) (4) (b) (4) (b) (4)	14 Jan 2021 23:59:08

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	14 Jan 2021 23:59:08

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'diabetes'	Brandon Illickal (b) (4)	14 Jan 2021 23:59:08

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered '1000'	Brandon Illickal (b) (4)	14 Jan 2021 23:59:08

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'mg (mg)'	Brandon Illickal (b) (4)	14 Jan 2021 23:59:08

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:28:30**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	14 Jan 2021 23:59:08

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'once daily (QD)'	Brandon Illickal (b) (4)	14 Jan 2021 23:59:08



US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:28:30**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	14 Jan 2021 23:59:08

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'Oral (ORAL)'	Brandon Illickal (b) (4)	14 Jan 2021 23:59:08

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:28:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	14 Jan 2021 23:59:08

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'un Jan 2010'	Brandon Illickal (b) (4)	14 Jan 2021 23:59:08

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	14 Jan 2021 23:59:08

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	14 Jan 2021 23:59:08

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	14 Jan 2021 23:59:08

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	14 Jan 2021 23:59:08



**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 23:59:08

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 23:59:08

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Jan 2021 23:59:08

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Jan 2021 00:15:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 00:15:59
Data point term sent to Coder	System	15 Jan 2021 00:00:46
User entered 'hydrochlorothiazide'	Brandon Illickal (b) (4) (b) (4) (b) (4)	15 Jan 2021 00:00:04

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:04

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'hypertension'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:04

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered '25'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:04

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'mg (mg)'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:04



US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:28:30**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:00:04

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'once daily (QD)'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:04

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:00:04

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'Oral (ORAL)'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:04

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:28:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:00:04

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'un Jan 2010'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:04

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:30

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:04

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:04



US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:00:04

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:04

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 00:00:04

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 00:00:04

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Jan 2021 00:00:04

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Feb 2021 15:51:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 15:51:48
Data point term sent to Coder	System	12 Feb 2021 15:50:48
Datapoint queued for coding (5254245).	System	12 Feb 2021 15:50:24
User entered 'lisinopril'	Brandon Illickal (b) (4) (b) (4) (b) (4)	15 Jan 2021 00:00:47

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:47

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'hypertension'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:47



US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:28:30**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered '10'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:47

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'mg (mg)'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:47

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:28:30**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:00:47

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'once daily (QD)'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:47

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:28:30**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:00:47

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:28:30**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Oral (ORAL)'	(b) (4)	
	Brandon Illickal (b) (4)	15 Jan 2021 00:00:47

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:28:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:00:47

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	15 Jan 2021 00:01:00
User entered 'UN Jan 2010' reason for change: Data Entry Error	System	15 Jan 2021 00:01:00
User entered 'UN Jan 2010' reason for change: Data Entry Error	Brandon Illickal (b) (4)	15 Jan 2021 00:01:00
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).		
User entered 'un 2010' (non-conformant).	System	15 Jan 2021 00:00:47
	Brandon Illickal (b) (4)	15 Jan 2021 00:00:47



US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:28:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:47

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:28:30**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:47

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:28:30**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:00:47

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	15 Jan 2021 00:00:47

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:28:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 00:00:47

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:28:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 00:00:47

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:28:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Jan 2021 00:00:47

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Feb 2021 15:51:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 15:51:49
Data point term sent to Coder	System	12 Feb 2021 15:50:48
Datapoint queued for coding (5254245).	System	12 Feb 2021 15:50:24
User entered 'carvedilol'	Brandon Illickal (b) (4) (b) (4) (b) (4)	15 Jan 2021 00:01:45



US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	15 Jan 2021 00:01:45

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'hypertension'	Brandon Illickal (b) (4)	15 Jan 2021 00:01:45

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered '12.5'	Brandon Illickal (b) (4)	15 Jan 2021 00:01:45

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'mg (mg)'	Brandon Illickal (b) (4)	15 Jan 2021 00:01:45

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:28:30**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:01:45

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'once daily (QD)'	Brandon Illickal (b) (4)	15 Jan 2021 00:01:45

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:01:45

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:28:30**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Oral (ORAL)'	(b) (4) Brandon Illickal (b) (4)	15 Jan 2021 00:01:45



US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:28:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:01:45

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'un Jan 2018'	Brandon Illickal (b) (4)	15 Jan 2021 00:01:45

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:30

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	15 Jan 2021 00:01:45

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	15 Jan 2021 00:01:45

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:28:30**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:01:45

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:28:30**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	15 Jan 2021 00:01:45

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:28:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 00:01:45

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:28:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 00:01:45



**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:28:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Jan 2021 00:01:45

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 00:03:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 00:03:59
Data point term sent to Coder	System	15 Jan 2021 00:03:18
User entered 'Trulicity'	Brandon Illickal (b) (4)	15 Jan 2021 00:02:28

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	15 Jan 2021 00:02:28

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'Diabetes'	Brandon Illickal (b) (4)	15 Jan 2021 00:02:28

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered '1.5'	Brandon Illickal (b) (4)	15 Jan 2021 00:02:28

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'mg (mg)'	Brandon Illickal (b) (4)	15 Jan 2021 00:02:28

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:02:28

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'every week (QS)'	Brandon Illickal (b) (4)	15 Jan 2021 00:02:28



US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:02:28

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Brandon Illickal (b) (4)	15 Jan 2021 00:02:28

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:28:30**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:02:28

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'un Jan 2018'	Brandon Illickal (b) (4)	15 Jan 2021 00:02:28

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:28:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	15 Jan 2021 00:02:28

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:28:30**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	15 Jan 2021 00:02:28

US3392251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	15 Jan 2021 00:02:28

US3392251

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:28:30**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	15 Jan 2021 00:02:28



**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:28:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 00:02:28

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:28:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 00:02:28

**US3392251**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:28:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	15 Jan 2021 00:02:28

US3392251

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:28:30

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Brandon Illickal (b) (4)	25 Feb 2021 01:49:19
User entered 'Yes (Y)' reason for change: New Information	Brandon Illickal (b) (4)	11 Feb 2021 07:35:27
User entered 'No (N)'	Brandon Illickal (b) (4)	15 Jan 2021 00:06:26

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'USA-US119-2020-MRNA-1273-P301000005'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Yes (Y)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51



**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Yes (Y)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Michael'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Cotugno'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:41:15
User entered 'US'	System	22 Oct 2020 16:20:40

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	07 Jan 2021 17:21:55
User entered '4'	System	29 Dec 2020 14:34:43
User entered '3'	System	11 Dec 2020 18:35:27
User entered '2'	System	30 Nov 2020 19:41:28
User entered '1'	System	22 Oct 2020 16:20:40



**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'USA-US119-2020-MRNA-1273-P301000005'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Yes (Y)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Yes (Y)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51



US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Michael'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Cotugno'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:41:15
User entered 'US'	System	22 Oct 2020 16:20:40

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	07 Jan 2021 17:21:55
User entered '4'	System	29 Dec 2020 14:34:43
User entered '3'	System	11 Dec 2020 18:35:27
User entered '2'	System	30 Nov 2020 19:41:28
User entered '1'	System	22 Oct 2020 16:20:40

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
User entered '22/Oct/2020 16:20'	System	22 Oct 2020 16:20:40

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:28:30

**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 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:41:15
User entered 'I'	(b) (4), (b) (6)	22 Oct 2020 16:20:40

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'USA-US119-2020-MRNA-1273-P301000005'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Yes (Y)'	System	22 Oct 2020 16:19:51



**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Yes (Y)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Michael'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Cotugno'	System	22 Oct 2020 16:19:51



**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:41:15
User entered 'US'	System	22 Oct 2020 16:20:40

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	07 Jan 2021 17:21:55
User entered '4'	System	29 Dec 2020 14:34:43
User entered '3'	System	11 Dec 2020 18:35:27
User entered '2'	System	30 Nov 2020 19:41:28
User entered '1'	System	22 Oct 2020 16:20:40

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:28:30**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
User entered '30/Nov/2020 14:41'	System	30 Nov 2020 19:41:28

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:28:30

**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 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 18:35:15
User entered 'I'	(b) (4), (b) (6)	30 Nov 2020 19:41:28

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'USA-US119-2020-MRNA-1273-P301000005'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Yes (Y)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51



**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Yes (Y)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Michael'	System	22 Oct 2020 16:19:51

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Cotugno'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:41:15
User entered 'US'	System	22 Oct 2020 16:20:40

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	07 Jan 2021 17:21:55
User entered '4'	System	29 Dec 2020 14:34:43
User entered '3'	System	11 Dec 2020 18:35:27
User entered '2'	System	30 Nov 2020 19:41:28
User entered '1'	System	22 Oct 2020 16:20:40



**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:28:30**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
User entered '11/Dec/2020 10:35'	System	11 Dec 2020 18:35:27

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:28:30

**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 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 14:34:21
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 18:35:27

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'USA-US119-2020-MRNA-1273-P301000005'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Yes (Y)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Yes (Y)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51



**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Michael'	System	22 Oct 2020 16:19:51

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Cotugno'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:41:15
User entered 'US'	System	22 Oct 2020 16:20:40

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	07 Jan 2021 17:21:55
User entered '4'	System	29 Dec 2020 14:34:43
User entered '3'	System	11 Dec 2020 18:35:27
User entered '2'	System	30 Nov 2020 19:41:28
User entered '1'	System	22 Oct 2020 16:20:40

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:28:30**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
User entered '29/Dec/2020 09:34'	System	29 Dec 2020 14:34:43

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:28:30

**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 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 14:35:23
User entered 'I'	(b) (4), (b) (6)	29 Dec 2020 14:34:43



**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'USA-US119-2020-MRNA-1273-P301000005'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Yes (Y)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Yes (Y)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'No (N)'	System	22 Oct 2020 16:19:51



US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Michael'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:20:30
User entered 'Cotugno'	System	22 Oct 2020 16:19:51

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 19:41:15
User entered 'US'	System	22 Oct 2020 16:20:40

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	07 Jan 2021 17:21:55
User entered '4'	System	29 Dec 2020 14:34:43
User entered '3'	System	11 Dec 2020 18:35:27
User entered '2'	System	30 Nov 2020 19:41:28
User entered '1'	System	22 Oct 2020 16:20:40

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:28:30**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:46
User entered '07/Jan/2021 17:21'	System	07 Jan 2021 17:21:55

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:28:30

**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 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:08:46
User entered 'I'	(b) (4), (b) (6)	07 Jan 2021 17:21:55

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered		
'USA-US119-2020-MRNA-1273-P301000012'	System	29 Dec 2020 15:07:59

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'Yes (Y)'	System	29 Dec 2020 15:07:59



**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'No (N)'	System	29 Dec 2020 15:07:59

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'No (N)'	System	29 Dec 2020 15:07:59

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'Yes (Y)'	System	29 Dec 2020 15:07:59

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'No (N)'	System	29 Dec 2020 15:07:59

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'No (N)'	System	29 Dec 2020 15:07:59

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'No (N)'	System	29 Dec 2020 15:07:59

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'Michael'	System	29 Dec 2020 15:07:59

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'Cotugno'	System	29 Dec 2020 15:07:59



**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'US'	System	29 Dec 2020 15:08:39

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Dec 2020 15:08:39

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered		
'USA-US119-2020-MRNA-1273-P301000012'	System	29 Dec 2020 15:07:59

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'Yes (Y)'	System	29 Dec 2020 15:07:59

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'No (N)'	System	29 Dec 2020 15:07:59

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'No (N)'	System	29 Dec 2020 15:07:59

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'Yes (Y)'	System	29 Dec 2020 15:07:59

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'No (N)'	System	29 Dec 2020 15:07:59



**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'No (N)'	System	29 Dec 2020 15:07:59

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'No (N)'	System	29 Dec 2020 15:07:59

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'Michael'	System	29 Dec 2020 15:07:59

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'Cotugno'	System	29 Dec 2020 15:07:59

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'US'	System	29 Dec 2020 15:08:39

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:28:30**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Dec 2020 15:08:39

**US3392251**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:28:30**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:09:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:08:58
User entered '29/Dec/2020 10:08'	System	29 Dec 2020 15:08:39

US3392251

Folder: SAE USA-US119-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:28:30

**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 20:09:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:08:58
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:08:45
User entered 'I'	(b) (4), (b) (6)	29 Dec 2020 15:08:39