

US3392120 (Prod: Benchmark Research - Metairie - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:25:38

All time stamps listed in this document are displayed in GMT

US3392120

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

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Participant ID

US3392120

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

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US3392120

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:12:44

Generated On: 09 Jun 2021 17:25:38

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

Visit date (dd MMM yyyy)	31 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3392120

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 03:12:44

Generated On: 09 Jun 2021 17:25:38

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	63
Age Units	YEARS
Age (Derived)	63
Sex	Female <input type="radio"/> Male <input checked="" 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

US3392120

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 03:12:44

Generated On: 09 Jun 2021 17:25:38

Date of Informed Consent ( <i>dd MMM yyyy</i> )	31 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input 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

US3392120

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 03:12:44

Generated On: 09 Jun 2021 17:25:38

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3392120

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 03:12:44

Generated On: 09 Jun 2021 17:25:38

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Were any significant conditions reported?

Yes ☒

No ☐

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US3392120

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	UN MAR 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAR 2009
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2009
Start Year (derived)	2009
Stop Month and Year (derived)	MAR 2009
Stop Year (derived)	2009

US3392120

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN MAR 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

US3392120

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN MAR 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3392120

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN MAR 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

US3392120

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN APR 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3392120

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

Condition	ANXIETY
Start date (dd MMM yyyy)	UN APR 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3392120

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 03:12:44

Generated On: 09 Jun 2021 17:25:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	31 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	08:47 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 08:47
Height ( <i>xxx.x</i> )	70 in
Weight ( <i>xxx.x</i> )	225 lb
BMI ( <i>xxx.x</i> )	32.35164 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 03:12:44

Generated On: 09 Jun 2021 17:25:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 20 Feb 2021 03:12:44

Generated On: 09 Jun 2021 17:25:38

Date of assessment (*dd MMM yyyy*)

Is the participant of childbearing potential?

Yes ☐

No ☐

If No, what is the reason?

Surgically sterile ☐

Post-menopausal ☐

Partner medically sterile ☐

Not reached age of Menarche ☐

Other ☐

If Partner medically sterile or Other, specify

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

Date of surgery unknown

False

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

Date of last menstruation unknown

False

US3392120

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 03:12:44

Generated On: 09 Jun 2021 17:25:38

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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**

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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 03:12:44

Generated On: 09 Jun 2021 17:25:38

<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)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	True
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

US3392120

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 02:51:52

Generated On: 09 Jun 2021 17:25:38

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

Visit date (dd MMM yyyy)	31 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3392120

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 02:51:52

Generated On: 09 Jun 2021 17:25:38

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 145362

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☐   
 >=18 and <65 years and at risk ☒   
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☒ No ☐

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 02:51:52

Generated On: 09 Jun 2021 17:25:38

Height	ND - Not Done
Weight	ND - Not Done

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 02:51:52

Generated On: 09 Jun 2021 17:25:38

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)	31 AUG 2020
Time of assessment (00:00-23:59)	08:47 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 08:47
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 02:51:52

Generated On: 09 Jun 2021 17:25:38

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)	31 AUG 2020
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 10:35
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3392120

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 02:51:52

Generated On: 09 Jun 2021 17:25:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 02:51:52

Generated On: 09 Jun 2021 17:25:38

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 10:04 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 10:04

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 02:51:52

Generated On: 09 Jun 2021 17:25:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 AUG 2020
Collection time (00:00-23:59)	09:45 (24 HR)
Collection date and time (derived)	31 AUG 2020 09:45

US3392120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 02:51:52

Generated On: 09 Jun 2021 17:25:38

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:40	31 AUG 2020 09:40
Nasopharyngeal Swab 2	No		

US3392120

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:51:52

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**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

31 AUG 2020 10:34

PC Open Date & Time

31 AUG 2020 10:24

PC Close Date & Time

31 AUG 2020 12:54

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	31 AUG 2020 14:29
PC Open Date & Time	31 AUG 2020 13:49
PC Close Date & Time	01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**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

01 SEP 2020 12:32

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**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

98.4 °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

02 SEP 2020 12:58

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**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

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

03 SEP 2020 13:05

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**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

97.9 °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

04 SEP 2020 12:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**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

98.4 °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

05 SEP 2020 13:23

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**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

99.1 °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

06 SEP 2020 15:18

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**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

31 AUG 2020 10:35

PC Open Date & Time

31 AUG 2020 10:24

PC Close Date & Time

31 AUG 2020 12:54

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**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

31 AUG 2020 14:27

PC Open Date & Time

31 AUG 2020 13:49

PC Close Date & Time

01 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**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

01 SEP 2020 12:31

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**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

02 SEP 2020 12:59

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**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

03 SEP 2020 13:04

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**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

04 SEP 2020 12:03

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**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

05 SEP 2020 13:23

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**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

06 SEP 2020 15:16

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**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 ☐

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 10:35
PC Open Date & Time	31 AUG 2020 10:24
PC Close Date & Time	31 AUG 2020 12:54

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**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 ☐

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 14:26
PC Open Date & Time	31 AUG 2020 13:49
PC Close Date & Time	01 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**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 ☒

PRODUCTION RELEASE (v12.003

50 of 2222

EAB) (1725)

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 12:31
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**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 ☒

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2222

EAB) (1725)

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 13:04
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2222

EAB) (1725)

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:03
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 2222

EAB) (1725)

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 13:23
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**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 ☒

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 15:16
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 8

Select one response below to indicate the level of your

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

PC Time stamp

07 SEP 2020 12:34

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3392120

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:25:38

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 SEP 2020 12:35
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3392120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:05:23

Generated On: 09 Jun 2021 17:25:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392120

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:05:23

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:32:01

Generated On: 09 Jun 2021 17:25:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392120

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:32:01

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:12:34

Generated On: 09 Jun 2021 17:25:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392120

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:12:34

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 04:50:28

Generated On: 09 Jun 2021 17:25:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT2

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 04:50:28

Generated On: 09 Jun 2021 17:25:38

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)	30 SEP 2020
Time of assessment (00:00-23:59)	08:06 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 08:06
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 04:50:28

Generated On: 09 Jun 2021 17:25:38

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)	30 SEP 2020
Time of assessment (00:00-23:59)	09:31 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 09:31
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3392120

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 04:50:28

Generated On: 09 Jun 2021 17:25:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3392120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 04:50:28

Generated On: 09 Jun 2021 17:25:38

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) 30 SEP 2020

What was the treatment time? (00:00-23:59) 08:52 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 08:52

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

US3392120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 04:50:28

Generated On: 09 Jun 2021 17:25:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 SEP 2020

Collection time (00:00-23:59)

08:30 (24 HR)

Collection date and time (derived)

30 SEP 2020 08:30

US3392120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 04:50:28

Generated On: 09 Jun 2021 17:25:38

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:25	30 SEP 2020 08:25
Nasopharyngeal Swab 2	No		

US3392120

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 04:50:28

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**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

30 SEP 2020 09:19

PC Open Date & Time

30 SEP 2020 09:12

PC Close Date & Time

30 SEP 2020 11:42

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	30 SEP 2020 18:37
PC Open Date & Time	30 SEP 2020 12:37
PC Close Date & Time	01 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**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

99.1 °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

01 OCT 2020 13:25

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**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

97.8 °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

02 OCT 2020 12:34

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 15:32

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 15:38

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**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

98.3 °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

05 OCT 2020 12:53

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**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

97.9 °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

06 OCT 2020 15:26

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**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

30 SEP 2020 09:20

PC Open Date & Time

30 SEP 2020 09:12

PC Close Date & Time

30 SEP 2020 11:42

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**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

30 SEP 2020 18:37

PC Open Date & Time

30 SEP 2020 12:37

PC Close Date & Time

01 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**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

01 OCT 2020 13:25

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**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

02 OCT 2020 12:32

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**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

03 OCT 2020 15:30

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**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

04 OCT 2020 15:36

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**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

05 OCT 2020 12:53

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**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

06 OCT 2020 15:24

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**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 ☐

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 09:21
PC Open Date & Time	30 SEP 2020 09:12
PC Close Date & Time	30 SEP 2020 11:42

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**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 ☐

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 18:36
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PC Open Date & Time	30 SEP 2020 12:37
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PC Close Date & Time	01 OCT 2020 11:59
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US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 13:24
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:33
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 15:30
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**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 ☒

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 15:38
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 12:53
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 15:24
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3392120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:56:10

Generated On: 09 Jun 2021 17:25:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392120

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:56:10

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:39:55

Generated On: 09 Jun 2021 17:25:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392120

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:39:55

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:22:34

Generated On: 09 Jun 2021 17:25:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392120

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:22:33

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 05:22:02

Generated On: 09 Jun 2021 17:25:38

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

Visit date (dd MMM yyyy)	02 NOV 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3392120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 05:22:02

Generated On: 09 Jun 2021 17:25:38

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) \_\_\_\_\_

US3392120

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 05:22:02

Generated On: 09 Jun 2021 17:25:38

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.*

US3392120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 05:22:02

Generated On: 09 Jun 2021 17:25:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 NOV 2020

Collection time (00:00-23:59)

12:31 (24 HR)

Collection date and time (derived)

02 NOV 2020 12:31

US3392120

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 05:22:02

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	31 OCT 2020 00:03:20
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3392120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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

07 NOV 2020 00:01:47

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3392120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 00:04:32

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2020 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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

25 NOV 2020 00:09:08

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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	02 DEC 2020 00:01:48
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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

09 DEC 2020 02:36:35

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 21:40:34

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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

25 DEC 2020 14:31:24

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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	30 DEC 2020 00:01:50
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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

06 JAN 2021 00:32:14

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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

15 JAN 2021 11:26:13

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JAN 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 152

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

27 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	03 FEB 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 FEB 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

17 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

24 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 187

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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07 MAR 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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14 MAR 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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

17 MAR 2021 11:35:45

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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

24 MAR 2021 12:29:03

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 09:43:33

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 00:14:22

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 APR 2021 00:17:27
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☒

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 APR 2021 19:24:47

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 00:02:26

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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="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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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13 JUN 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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20 JUN 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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="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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	30 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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="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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

11 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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22 AUG 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59
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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	15 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	22 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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03 OCT 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	06 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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20 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 OCT 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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31 OCT 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	10 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2021 23:59
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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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="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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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12 DEC 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	15 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 DEC 2021 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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26 DEC 2021 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JAN 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 FEB 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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 <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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	16 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 MAR 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	06 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 APR 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 APR 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 APR 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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="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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	01 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUN 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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="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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	08 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUN 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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26 JUN 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

29 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	06 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 JUL 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUL 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

20 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JUL 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	10 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59
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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	17 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 AUG 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	24 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59
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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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="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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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18 SEP 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 SEP 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

28 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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="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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

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09 OCT 2022 23:59

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US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**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 ☐

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 OCT 2022 23:59

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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

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[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

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US3392120

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:25:38

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		16 MAR 2021 12:05:42

US3392120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:56:03

Generated On: 09 Jun 2021 17:25:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392120

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:56:03

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392120

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392120

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392120

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392120

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392120

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:17:07

Generated On: 09 Jun 2021 17:25:38

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

Visit date (dd MMM yyyy)	16 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
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US3392120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:17:07

Generated On: 09 Jun 2021 17:25:38

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) \_\_\_\_\_

US3392120

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:17:07

Generated On: 09 Jun 2021 17:25:38

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.*

US3392120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:17:07

Generated On: 09 Jun 2021 17:25:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 MAR 2021
Collection time (00:00-23:59)	11:15 (24 HR)
Collection date and time (derived)	16 MAR 2021 11:15

US3392120

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:17:07

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392120

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392120

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3392120**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

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*

**US3392120**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

Date of Contact	22 SEP 2020
Time of Contact	16:00
Date and Time of Contact (derived)	22 SEP 2020 16:00
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

Symptom Day

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

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

Symptom Day

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

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

Symptom Day

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

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	24 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

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

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

Symptom Day

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

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

Date of Visit	22 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	22 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

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[Generate Next COVID-19 Assessment](#)

Yes ☒  
No ☐

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US3392120

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

**US3392120**

**Folder: Illness Visit (2)**

**Form: Saliva Collection**

**Generated On: 09 Jun 2021 17:25:38**

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

US3392120

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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	SICKD1

US3392120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	16:10 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 16:10
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.0 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3392120

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3392120

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

22 SEP 2020

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3392120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:38

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.*

**US3392120**

**Folder: Illness Visit Day 1 (1)**

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

**Generated On: 09 Jun 2021 17:25:38**

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

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

**US3392120**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3392120

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:38

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.*

**US3392120**

**Folder: Convalescence Visit Day 28 (1)**

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

**Generated On: 09 Jun 2021 17:25:38**

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection \_\_\_\_\_

US3392120

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

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

Visit date (dd MMM yyyy)	15 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3392120

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Date of updated informed consent (dd MMM yyyy) 15 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 15 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3392120

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 JAN 2021

Collection time (00:00-23:59)

10:53 (24 HR)

Collection date and time (derived)

15 JAN 2021 10:53

US3392120

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 22:17:06

Generated On: 09 Jun 2021 17:25:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	10:55
Collection Date and Time (derived)	15 JAN 2021 10:55

US3392120

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 22:06:06

Generated On: 09 Jun 2021 17:25:38

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3392120

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:06:06

Generated On: 09 Jun 2021 17:25:38

AEID	USA-US119-2020-MRNA-1273-P30 1000006
Adverse event	MYOCARDIAL INFARCTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 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)	26 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 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)	24 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	26 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:06:06

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:06:06

Generated On: 09 Jun 2021 17:25:38

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PRESENTED TO ER WITH CHEST  
PAIN , DX'D WITH AMI FOR  
WHICH HE UNDERWENT  
EMERGENT PTCA X 2  
(RCA LESIONS); ADMITTED X 2  
NIGHTS.  
NO ICU. NOW ASYMPTOMATIC.  
SUBJECT HAS A MEDICAL  
HISTORY OF MYOCARDIAL  
INFARCTION.

---

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

---

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:06:06

Generated On: 09 Jun 2021 17:25:38

AEID	
Adverse event	TYPE II DIABETES
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:06:06

Generated On: 09 Jun 2021 17:25:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:06:06

Generated On: 09 Jun 2021 17:25:38

AEID	
Adverse event	MUSCLE SPASMS, RIGHT LEG
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)	10 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Apr 2021 20:05:54

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

Yes ☒

No ☐

---

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

---

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:05:53

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Name of Medication FINASTERIDE

Prophylaxis Yes ☐  
No ☒

Indication URINARY RETENTION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

	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 OCT 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 20:05:53

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Name of Medication SPIRONOLATONE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

	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 OCT 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

Name of Medication METOPROLOL TARTATE

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 20:05:53

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Name of Medication ATORVASTATINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2009	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 20:05:53

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Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

	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 APR 2009	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

Name of Medication DELSTROGEN

Prophylaxis Yes ☐  
No ☒

Indication GENDER DYSPHORIA

Dose per administration 0.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 20:05:53

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Name of Medication BRILINTA

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 20:05:53

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Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication WORSENING OF  
CARDIOVASCULAR  
DISEASE/SECONDARY TO  
MYOCARDIAL INFARCTION

Dose per administration 81

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 20:05:53

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Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE SPASMS, RIGHT LEG

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE SPASMS, RIGHT LEG

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

399 of 2222

EAB) (1725)

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

Name of Medication TICAGRELOR

Prophylaxis Yes ☒  
No ☐

Indication WORSENING OF  
CARDIOVASCULAR  
DISEASE/SECONDARY TO  
MYOCARDIAL INFARCTION

Dose per administration 90

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 20:05:53

Generated On: 09 Jun 2021 17:25:38

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3392120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3392120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
26 OCT 2020	PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY, RIGHT CORONARY ARTERY	Adverse Event	

US3392120

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:25:38

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

US3392120

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:25:38

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 ☐

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

SAEID	USA-US119-2020-MRNA-1273-P301000006
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)	4

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

SAEID	USA-US119-2020-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	03/NOV/2020 19:54
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

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

SAEID	USA-US119-2020-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	17/NOV/2020 08:28
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

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

SAEID	USA-US119-2020-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	30/NOV/2020 15:07
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

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 20:05:54

Generated On: 09 Jun 2021 17:25:38

SAEID	USA-US119-2020-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	17/MAR/2021 12:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3392120 (Prod: Benchmark Research - Metairie - PPDS)

**US3392120**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:25:38**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'US3392120'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 13:59:59

US3392120

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:25:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	31 Aug 2020 14:57:36

US3392120

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 14:00:04

US3392120

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:25:38

[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 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'Clinic (Clinic)'	Brenda Lawson (b) (4)	31 Aug 2020 14:57:36

**US3392120**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User entered 'SCRN'	System	31 Aug 2020 14:57:36

US3392120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered (b) (6) 1957'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 14:00:05

US3392120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '63'	Brenda Lawson (b) (4)	31 Aug 2020 14:57:56

**US3392120**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:38**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered 'YEARS'	System	31 Aug 2020 14:57:56

**US3392120**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:38**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '63'	System	31 Aug 2020 14:58:18

US3392120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:38

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User closed query 'Per GCL Lab Reconciliation RQ : Please clarify the sex of Male or Female is correct. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 10:18:34
Query 'Per GCL Lab Reconciliation RQ : Please clarify the sex of Male or Female is correct. Thank you.' answered with 'SUBJECT IS A MALE' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 21:38:04
User opened query 'Per GCL Lab Reconciliation RQ : Please clarify the sex of Male or Female is correct. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:50:31
User closed query 'Per GCL Lab Reconciliation: Swab Re-query: Sex (Male) recorded on this form does not match with the Sex (Female) reported in "PPD Central lab". Please reconcile the correct Sex and updated or else please confirm the "correct Sex". Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:50:31
Query 'Per GCL Lab Reconciliation: Swab Re-query: Sex (Male) recorded on this form does not match with the Sex (Female) reported in "PPD Central lab". Please reconcile the correct Sex and updated or else please confirm the "correct Sex". Else clarify, thank you' answered with 'SEX IS CORRECT' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 18:45:51
User opened query 'Per GCL Lab Reconciliation: Swab Re-query: Sex (Male) recorded on this form does not match with the Sex (Female) reported in "PPD Central lab". Please reconcile the correct Sex and updated or else please confirm the "correct Sex". Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 09:20:32
User closed query 'Per GCL Lab Reconciliation: Swab for Visit1 Day, Visit2 Day29 1 Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 09:07:05
User entered 'Male (M)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 20:46:14

US3392120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:38

Sex

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab for Visit1 Day, Visit2 Day29 1 Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' answered with 'data corrected' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 20:42:47
User entered 'Female (F)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 20:42:33
User opened query 'Per GCL Lab Reconciliation: Swab for Visit1 Day, Visit2 Day29 1 Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 11:55:48
User entered 'Male (M)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	30 Sep 2020 13:57:20
User entered 'Female (F)'	Brenda Lawson (b) (4)	31 Aug 2020 14:57:56

US3392120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brenda Lawson (b) (4)	31 Aug 2020 14:57:56

**US3392120**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:38**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'I'	Brenda Lawson (b) (4)	31 Aug 2020 14:57:56

**US3392120**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:38**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 14:57:56

**US3392120**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:38**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 14:57:56

**US3392120**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:38**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 14:57:56

US3392120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 14:57:56

**US3392120**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:38**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 14:57:56

US3392120

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:38

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 14:57:56

**US3392120**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:38**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 14:57:56

**US3392120**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:38**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 14:57:56

US3392120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '31 Aug 2020'	Brenda Lawson (b) (4)	31 Aug 2020 14:58:18

**US3392120**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered 'Aug 2020'	System	31 Aug 2020 14:58:18

**US3392120**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '2020'	System	31 Aug 2020 14:58:18

US3392120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:47:30
Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	21 Sep 2020 21:11:48
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	21 Sep 2020 21:11:43
User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:04:01
User entered 'Amendment 5 (5)'	Brenda Lawson (b) (4) (b) (4)	31 Aug 2020 14:58:18

US3392120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	31 Aug 2020 14:58:18

US3392120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:38

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 14:58:18

US3392120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 14:58:18

US3392120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 14:58:18

**US3392120**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:25:38**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 14:00:04

US3392120

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered 'I'	System	31 Aug 2020 14:58:23

US3392120

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	31 Aug 2020 14:58:23

US3392120

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:25:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	31 Aug 2020 14:58:37

US3392120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	31 Aug 2020 22:42:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 22:42:40
Data point term sent to Coder	System	31 Aug 2020 22:41:21
User entered 'myocardial infarction'	Brandon Illickal (b) (4)	31 Aug 2020 22:41:16

US3392120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'un Mar 2009'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:41:16

US3392120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:41:16

US3392120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'No (N)'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:41:16

US3392120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'un Mar 2009'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:41:16

US3392120

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:41:16

**US3392120**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered 'Mar 2009'	System	31 Aug 2020 22:41:16

**US3392120**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '2009'	System	31 Aug 2020 22:41:16

**US3392120**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered 'Mar 2009'	System	31 Aug 2020 22:41:16

**US3392120**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '2009'	System	31 Aug 2020 22:41:16

US3392120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:43:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:43:35
Data point term sent to Coder	System	31 Aug 2020 22:42:23
User entered 'coronary artery disease'	Brandon Illickal (b) (4)	31 Aug 2020 22:41:43

US3392120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'un Mar 2009'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:41:43

US3392120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:41:43

US3392120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'Yes (Y)'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:41:43

US3392120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty.	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:41:43

US3392120

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:41:43

**US3392120**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered 'Mar 2009'	System	31 Aug 2020 22:41:43

**US3392120**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '2009'	System	31 Aug 2020 22:41:43

**US3392120**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	System	31 Aug 2020 22:41:43

**US3392120**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	System	31 Aug 2020 22:41:43

US3392120

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 09:36:55
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'DATA ENTERED' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 20:28:01
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 08:19:26
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)	31 Aug 2020 22:44:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 22:44:36
Data point term sent to Coder	System	31 Aug 2020 22:43:23
User entered 'hypertension'	Brandon Illickal (b) (4)	31 Aug 2020 22:42:25

US3392120

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'un Mar 2009'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:42:25

US3392120

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:42:25

US3392120

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'Yes (Y)'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:42:25

US3392120

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty.	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:42:25

US3392120

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:42:25

**US3392120**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered 'Mar 2009'	System	31 Aug 2020 22:42:25

**US3392120**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '2009'	System	31 Aug 2020 22:42:25

**US3392120**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	System	31 Aug 2020 22:42:25

**US3392120**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	System	31 Aug 2020 22:42:25

US3392120

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Aug 2020 22:45:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:45:35
Data point term sent to Coder	System	31 Aug 2020 22:45:26
User entered 'hypercholesterolemia'	Brandon Illickal (b) (4)	31 Aug 2020 22:44:38

US3392120

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'un Mar 2009'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:44:38

US3392120

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brandon Illickal (b) (4)	31 Aug 2020 22:44:38

US3392120

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'Yes (Y)'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:44:38

US3392120

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty.	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:44:38

US3392120

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:44:38

**US3392120**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered 'Mar 2009'	System	31 Aug 2020 22:44:38

**US3392120**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '2009'	System	31 Aug 2020 22:44:38

**US3392120**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	System	31 Aug 2020 22:44:38

**US3392120**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	System	31 Aug 2020 22:44:38

US3392120

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:45:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:45:35
Data point term sent to Coder	System	31 Aug 2020 22:45:27
User entered 'depression'	Brandon Illickal (b) (4)	31 Aug 2020 22:45:08

US3392120

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'un Apr 2009'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:45:08

US3392120

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:45:08

**US3392120**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:25:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'Yes (Y)'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:45:08

US3392120

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty.	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:45:08

US3392120

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:45:08

US3392120

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered 'Apr 2009'	System	31 Aug 2020 22:45:08

**US3392120**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '2009'	System	31 Aug 2020 22:45:08

**US3392120**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	System	31 Aug 2020 22:45:08

**US3392120**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	System	31 Aug 2020 22:45:08

US3392120

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:45:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 22:45:34
Data point term sent to Coder	System	31 Aug 2020 22:45:27
User entered 'anxiety'	Brandon Illickal (b) (4)	31 Aug 2020 22:45:26

US3392120

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'un Apr 2009'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:45:26

US3392120

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:45:26

US3392120

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'Yes (Y)'	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:45:26

US3392120

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty.	(b) (4)	
	Brandon Illickal (b) (4)	31 Aug 2020 22:45:26

US3392120

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:45:26

US3392120

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered 'Apr 2009'	System	31 Aug 2020 22:45:26

**US3392120**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '2009'	System	31 Aug 2020 22:45:26

**US3392120**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	System	31 Aug 2020 22:45:26

**US3392120**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	System	31 Aug 2020 22:45:26

US3392120

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:42:17
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 00:46:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 00:46:04
Data point term sent to Coder	System	25 Feb 2021 00:45:03
User entered 'urinary retention'	Brandon Illickal (b) (4)	25 Feb 2021 00:44:56

US3392120

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:42:17
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	25 Feb 2021 00:45:10
User entered 'un Oct 2014' reason for change: Data Entry Error	Brandon Illickal (b) (4)	25 Feb 2021 00:45:10
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	25 Feb 2021 00:44:56
User entered empty.	Brandon Illickal (b) (4)	25 Feb 2021 00:44:56

US3392120

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '0'	Brandon Illickal (b) (4)	25 Feb 2021 00:44:56

US3392120

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:42:17
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 00:45:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 00:45:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	25 Feb 2021 00:45:10
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 00:44:56
User entered empty.	Brandon Illickal (b) (4)	25 Feb 2021 00:44:56

US3392120

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	Brandon Illickal (b) (4)	25 Feb 2021 00:44:56

US3392120

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '0'	Brandon Illickal (b) (4)	25 Feb 2021 00:44:56

US3392120

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered 'Oct 2014'	System	25 Feb 2021 00:45:10
User entered empty.	System	25 Feb 2021 00:44:56

US3392120

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '2014'	System	25 Feb 2021 00:45:10
User entered empty.	System	25 Feb 2021 00:44:56

**US3392120**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	System	25 Feb 2021 00:44:56

**US3392120**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	System	25 Feb 2021 00:44:56

US3392120

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:42:17
User coded data point as SOC: Psychiatric disorders, HLT: Sexual dysfunctions, disturbances and gender identity disorders, HLT: Sexual and gender identity disorders NEC, PT: Gender dysphoria, LLT: Gender dysphoria - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 22:08:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 22:08:59
Data point term sent to Coder	System	16 Mar 2021 22:08:25
User entered 'gender dysphoria'	Brandon Illickal (b) (4)	16 Mar 2021 22:08:06

US3392120

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered 'un Oct 2014'	Brandon Illickal (b) (4)	16 Mar 2021 22:08:06

US3392120

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:08:06

**US3392120**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:25:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	16 Mar 2021 22:08:06

US3392120

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:08:06

US3392120

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:08:06

US3392120

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered 'Oct 2014'	System	16 Mar 2021 22:08:06

**US3392120**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered '2014'	System	16 Mar 2021 22:08:06

**US3392120**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	System	16 Mar 2021 22:08:06

**US3392120**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:10:21
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:10:25
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User entered empty.	System	16 Mar 2021 22:08:06

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	31 Aug 2020 15:00:58

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '31 Aug 2020'	Brenda Lawson (b) (4)	31 Aug 2020 15:00:58

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '08:47'	Brenda Lawson (b) (4)	31 Aug 2020 15:00:58

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User entered '31 Aug 2020 08:47'	System	31 Aug 2020 15:00:58

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '70' in	Brenda Lawson (b) (4)	31 Aug 2020 15:00:58
DataPoint set to visible.	System	31 Aug 2020 14:58:23

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '225' lb	Brenda Lawson (b) (4)	31 Aug 2020 15:00:58
DataPoint set to visible.	System	31 Aug 2020 14:58:23

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User entered '32.35164'	System	31 Aug 2020 15:00:58
DataPoint set to visible.	System	31 Aug 2020 14:58:23

**US3392120**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User entered 'kg/m2'	System	31 Aug 2020 15:00:58
DataPoint set to visible.	System	31 Aug 2020 14:58:23

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
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 17:46:57
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 18:08:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 18:08:34
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 18:20:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 15:01:09
User entered '98.4' F reason for change: Data Entry Error	Brenda Lawson (b) (4)	31 Aug 2020 15:01:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 15:00:58
User entered '98.4' (non-conformant).	Brenda Lawson (b) (4)	31 Aug 2020 15:00:58

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 18:08:34
User entered 'Oral (Oral)'	(b) (4) Brenda Lawson (b) (4)	31 Aug 2020 15:00:58

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:00:58

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 18:08:34
User entered '70'	Brenda Lawson (b) (4)	31 Aug 2020 15:00:58

**US3392120**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User entered 'bpm'	System	31 Aug 2020 15:00:58

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 18:08:34
User entered '14'	Brenda Lawson (b) (4)	31 Aug 2020 15:00:58

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User entered 'breaths/min'	System	31 Aug 2020 15:00:58

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 18:08:34
User entered '118'	(b) (4) Brenda Lawson (b) (4)	31 Aug 2020 15:00:58

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User entered 'mmHg'	System	31 Aug 2020 15:00:58

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 18:08:34
User entered '64'	Brenda Lawson (b) (4)	31 Aug 2020 15:00:58

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User entered 'mmHg'	System	31 Aug 2020 15:00:58

**US3392120**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22

US3392120

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22

US3392120

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	31 Aug 2020 15:01:18

US3392120

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '31 Aug 2020'	Brenda Lawson (b) (4)	31 Aug 2020 15:01:18

US3392120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:25:38

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 13:32:33
User closed query 'Per CDM: Sex is recoded as 'Male'. However childbearing potential recorded as 'NO'. Please review and delete the information to allow inactivation of page.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 13:32:31
Query 'Data is required. Please complete.' answered with 'information removed per query resolution' (Site from System).	Brandon Illickal (b) (4)	20 Jan 2021 20:10:48
Query 'Per CDM: Sex is recoded as 'Male'. However childbearing potential recorded as 'NO'. Please review and delete the information to allow inactivation of page.' answered with 'information removed per query resolution' (Site from DM).	Brandon Illickal (b) (4)	20 Jan 2021 20:10:45
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 20:10:28
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	20 Jan 2021 20:10:28
User opened query 'Per CDM: Sex is recoded as 'Male'. However childbearing potential recorded as 'NO'. Please review and delete the information to allow inactivation of page.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 19:40:32
User entered '31 Aug 2020'	Brenda Lawson (b) (4)	31 Aug 2020 15:02:27
	(b) (4)	

US3392120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:32:36
Query 'Data is required. Please complete.' answered with 'information removed per query resolution' (Site from System).	Brandon Illickal (b) (4)	20 Jan 2021 20:10:52
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 20:10:28
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	20 Jan 2021 20:10:28
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:02:27

US3392120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	20 Jan 2021 20:10:28
User entered 'Other (OTHER)'	(b) (4) Brenda Lawson (b) (4)	31 Aug 2020 15:02:27

US3392120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:25:38

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	20 Jan 2021 20:10:28
User entered 'TRANSGENDER MALE TO FEMALE' reason for change: Data Entry Error	Brandon Illickal (b) (4)	30 Sep 2020 13:59:05
User entered 'TRANSGENDER MALE' reason for change: Data Entry Error	Brandon Illickal (b) (4)	30 Sep 2020 13:57:54
User entered 'Tran gender male'	Brenda Lawson (b) (4)	31 Aug 2020 15:02:27

US3392120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:02:27

**US3392120**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:25:38**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 15:02:27

US3392120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:02:27

US3392120

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:25:38

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 15:02:27

US3392120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

US3392120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

US3392120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:38

**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)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

US3392120

Folder: Screening

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**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)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

US3392120

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

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Folder: Screening

Form: Risk of Exposure

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**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)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

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Folder: Screening

Form: Risk of Exposure

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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)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

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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)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

US3392120

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)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

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Folder: Screening

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)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

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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)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

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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)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

US3392120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

US3392120

Folder: Screening

Form: Risk of Exposure

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**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)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

US3392120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:38

[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)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:38

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)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered 'I'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

US3392120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

US3392120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered '0'	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

US3392120

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:42:22
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:12:44
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:03:00

**US3392120**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	31 Aug 2020 15:05:21

**US3392120**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '31 Aug 2020'	Brenda Lawson (b) (4)	31 Aug 2020 15:05:21

US3392120

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'Clinic (Clinic)'	Brenda Lawson (b) (4)	31 Aug 2020 15:05:21

**US3392120**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'VISIT1'	System	31 Aug 2020 15:05:21

US3392120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 14:20:02

US3392120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:38

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '145362'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 14:20:02

US3392120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 14:20:02

US3392120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:05:36

US3392120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	31 Aug 2020 15:05:36

US3392120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:05:36

US3392120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:38

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:05:36

US3392120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'No (N)'	Brenda Lawson (b) (4)	31 Aug 2020 15:05:36

US3392120

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:38

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	22 Sep 2020 17:07:18
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:41:25
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:41:24

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
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 17:46:58
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 16:11:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:11:23
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 18:20:15
User entered '70' in	Brenda Lawson (b) (4) (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 16:11:23
User entered '225.0' lb	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
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 17:46:58
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 16:11:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:11:23
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 18:20:15
User entered '70' in	Brenda Lawson (b) (4) (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 16:11:23
User entered '225.0' lb	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Lawson (b) (4) (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '31 Aug 2020'	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '08:47'	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered '31 Aug 2020 08:47'	System	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '98.4' F	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'Oral (Oral)'	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Aug 2020 22:46:15
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	31 Aug 2020 22:46:15
User entered '70' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	31 Aug 2020 22:46:15
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:06:37
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'bpm'	System	31 Aug 2020 22:46:15
User entered empty.	System	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Aug 2020 22:46:15
Query 'Data is required. Please provide.' answered by System	System	31 Aug 2020 22:46:15
data change (Site from System).		
User entered '14' reason for change: New Information	Brandon Illickal (b) (4)	31 Aug 2020 22:46:15
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:06:37
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'breaths/min'	System	31 Aug 2020 22:46:15
User entered empty.	System	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Aug 2020 22:46:15
Query 'Data is required. Please provide.' answered by System	System	31 Aug 2020 22:46:15
data change (Site from System).		
User entered '118' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	31 Aug 2020 22:46:15
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:06:37
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'mmHg'	System	31 Aug 2020 22:46:15
User entered empty.	System	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Aug 2020 22:46:15
Query 'Data is required. Please provide.' answered by System	System	31 Aug 2020 22:46:15
data change (Site from System).		
User entered '64' reason for change: Data Entry Error	Brandon Illickal (b) (4)	31 Aug 2020 22:46:15
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:06:37
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'mmHg'	System	31 Aug 2020 22:46:15
User entered empty.	System	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
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 17:46:58
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 16:11:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:11:23
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 18:20:15
User entered '70' in	Brenda Lawson (b) (4) (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 16:11:23
User entered '225.0' lb	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Lawson (b) (4) (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 22:47:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 22:47:13
User entered 'Yes (Y)' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	31 Aug 2020 22:47:13
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:06:37
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '31 Aug 2020' reason for change: Per Query Resolution	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:47:13
User entered empty.	(b) (4) Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '10:35' reason for change: Per Query Resolution	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:47:13
User entered empty.	(b) (4) Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered '31 Aug 2020 10:35'	System	31 Aug 2020 22:47:13
User entered empty.	System	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '98.4' F reason for change: Per Query Resolution	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:47:13
User entered empty.	(b) (4) Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'Oral (Oral)' reason for change: Per Query Resolution	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:47:13
User entered empty.	(b) (4) Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '70' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:47:13
User entered empty.	(b) (4) Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'bpm'	System	31 Aug 2020 22:47:13
User entered empty.	System	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '14' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:47:13
User entered empty.	(b) (4) Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'breaths/min'	System	31 Aug 2020 22:47:13
User entered empty.	System	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '118' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:47:13
User entered empty.	(b) (4) Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'mmHg'	System	31 Aug 2020 22:47:13
User entered empty.	System	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '68' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	31 Aug 2020 22:47:13
User entered empty.	(b) (4) Brenda Lawson (b) (4)	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'mmHg'	System	31 Aug 2020 22:47:13
User entered empty.	System	31 Aug 2020 15:06:37

US3392120

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	31 Aug 2020 15:06:48

US3392120

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '31 Aug 2020'	Brenda Lawson (b) (4)	31 Aug 2020 15:06:48

US3392120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	31 Aug 2020 15:22:55

US3392120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:22:55

US3392120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:22:55

US3392120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 15:22:55

US3392120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '31 Aug 2020'	Brenda Lawson (b) (4)	31 Aug 2020 15:22:55

US3392120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '10:04'	Brenda Lawson (b) (4)	31 Aug 2020 15:22:55

US3392120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered '31 Aug 2020 10:04'	System	31 Aug 2020 15:22:55

US3392120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'Left Arm (LEFT ARM)'	Brenda Lawson (b) (4)	31 Aug 2020 15:22:55

US3392120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'ONCE'	System	31 Aug 2020 15:22:55

US3392120

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 15:22:55

US3392120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	31 Aug 2020 15:28:29

US3392120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '31 Aug 2020'	Brenda Lawson (b) (4)	31 Aug 2020 15:28:29

US3392120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '09:45'	Brenda Lawson (b) (4)	31 Aug 2020 15:28:29

US3392120

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered '31 Aug 2020 09:45'	System	31 Aug 2020 15:28:29

US3392120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:25:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '31 Aug 2020'	Brenda Lawson (b) (4)	31 Aug 2020 15:28:49

US3392120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Lawson (b) (4) (b) (4)	31 Aug 2020 15:28:49

US3392120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	31 Aug 2020 15:28:49

US3392120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered '09:40'	Brenda Lawson (b) (4)	31 Aug 2020 15:28:49

**US3392120**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered '31 Aug 2020 09:40'	System	31 Aug 2020 15:28:49

US3392120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Lawson (b) (4) (b) (4)	31 Aug 2020 15:28:49

US3392120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Sep 2020 15:22:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 15:22:29
User entered 'No (N)' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	01 Sep 2020 15:22:29
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:28:49
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:28:49

US3392120

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered empty.	Brenda Lawson (b) (4)	31 Aug 2020 15:28:49

**US3392120**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered empty.	System	31 Aug 2020 15:28:49

US3392120

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:51:53
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	31 Aug 2020 15:28:57

**US3392120**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'I'	System	31 Aug 2020 15:28:57

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:34:08', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '71fe7d52-958d-41bd-bff5-29f24a08e9ca' User entered 'Yes (Y)'	System	31 Aug 2020 15:34:29
	System	31 Aug 2020 15:34:29

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:34:17', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '71fe7d52-958d-41bd-bff5-29f24a08e9ca' User entered '98.4'	System	31 Aug 2020 15:34:29
	System	31 Aug 2020 15:34:29

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:34:21', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '71fe7d52-958d-41bd-bff5-29f24a08e9ca'	System	31 Aug 2020 15:34:29
User entered 'No (N)'	System	31 Aug 2020 15:34:29

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:34:25', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '71fe7d52-958d-41bd-bff5-29f24a08e9ca' User entered '31 Aug 2020 10:34'	System	31 Aug 2020 15:34:29
	System	31 Aug 2020 15:34:29

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '31 Aug 2020 10:24'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '31 Aug 2020 12:54'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:29:05', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '0d598ef9-e15d-40e1-b641-0d501eb88864' User entered 'Yes (Y)'	System	31 Aug 2020 19:31:51
	System	31 Aug 2020 19:31:51

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:29:13', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '0d598ef9-e15d-40e1-b641-0d501eb88864' User entered '98.4'	System	31 Aug 2020 19:31:51
	System	31 Aug 2020 19:31:51

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:29:17', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '0d598ef9-e15d-40e1-b641-0d501eb88864' User entered 'No (N)'	System	31 Aug 2020 19:31:51
	System	31 Aug 2020 19:31:51

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:29:21', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '0d598ef9-e15d-40e1-b641-0d501eb88864' User entered '31 Aug 2020 14:29'	System	31 Aug 2020 19:31:51
	System	31 Aug 2020 19:31:51

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '31 Aug 2020 13:49'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 2'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:31:41', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'fea2cb65-5cf5-4086-a10f-53b6f2dac2bc'	System	01 Sep 2020 17:32:01
User entered 'Yes (Y)'	System	01 Sep 2020 17:32:01

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:31:54', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'fea2cb65-5cf5-4086-a10f-53b6f2dac2bc' User entered '98.0'	System	01 Sep 2020 17:32:01
	System	01 Sep 2020 17:32:01

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:31:57', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'fea2cb65-5cf5-4086-a10f-53b6f2dac2bc'	System	01 Sep 2020 17:32:01
User entered 'No (N)'	System	01 Sep 2020 17:32:01

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:32:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'fea2cb65-5cf5-4086-a10f-53b6f2dac2bc'	System	01 Sep 2020 17:32:01
User entered '01 Sep 2020 12:32'	System	01 Sep 2020 17:32:01

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 3'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:58:36', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ab3a7a7e-a02f-4543-9fa7-d88a7fd78340' User entered 'Yes (Y)'	System	02 Sep 2020 17:58:54
	System	02 Sep 2020 17:58:54

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:58:45', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ab3a7a7e-a02f-4543-9fa7-d88a7fd78340' User entered '98.4'	System	02 Sep 2020 17:58:54
	System	02 Sep 2020 17:58:54

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:58:49', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ab3a7a7e-a02f-4543-9fa7-d88a7fd78340'	System	02 Sep 2020 17:58:54
User entered 'No (N)'	System	02 Sep 2020 17:58:54

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:58:52', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ab3a7a7e-a02f-4543-9fa7-d88a7fd78340' User entered '02 Sep 2020 12:58'	System	02 Sep 2020 17:58:54
	System	02 Sep 2020 17:58:54

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 4'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:05:14', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'cb15ac0f-638e-49ed-ae57-8ed7d60410f2'	System	03 Sep 2020 18:05:28
User entered 'Yes (Y)'	System	03 Sep 2020 18:05:28

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:05:19', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'cb15ac0f-638e-49ed-ae57-8ed7d60410f2'	System	03 Sep 2020 18:05:28
User entered '98.4'	System	03 Sep 2020 18:05:28

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:05:22', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'cb15ac0f-638e-49ed-ae57-8ed7d60410f2'	System	03 Sep 2020 18:05:28
User entered 'No (N)'	System	03 Sep 2020 18:05:28

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:05:25', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'cb15ac0f-638e-49ed-ae57-8ed7d60410f2'	System	03 Sep 2020 18:05:28
User entered '03 Sep 2020 13:05'	System	03 Sep 2020 18:05:28

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 5'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:04:28', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5c0521e4-491d-4032-a2fc-4654451ee9b9'	System	04 Sep 2020 17:05:56
User entered 'Yes (Y)'	System	04 Sep 2020 17:05:56

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:05:40', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5c0521e4-491d-4032-a2fc-4654451ee9b9' User entered '97.9'	System	04 Sep 2020 17:05:56
	System	04 Sep 2020 17:05:56

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:05:43', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5c0521e4-491d-4032-a2fc-4654451ee9b9'	System	04 Sep 2020 17:05:56
User entered 'No (N)'	System	04 Sep 2020 17:05:56

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:05:46', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5c0521e4-491d-4032-a2fc-4654451ee9b9' User entered '04 Sep 2020 12:05'	System	04 Sep 2020 17:05:56
	System	04 Sep 2020 17:05:56

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 6'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:38', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '77b97479-72b6-407a-982d-672d3f37dace' User entered 'Yes (Y)'	System	05 Sep 2020 18:24:00
	System	05 Sep 2020 18:24:00

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:50', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '77b97479-72b6-407a-982d-672d3f37dace' User entered '98.4'	System	05 Sep 2020 18:24:00
	System	05 Sep 2020 18:24:00

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:53', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '77b97479-72b6-407a-982d-672d3f37dace'	System	05 Sep 2020 18:24:00
User entered 'No (N)'	System	05 Sep 2020 18:24:00

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:55', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '77b97479-72b6-407a-982d-672d3f37dace' User entered '05 Sep 2020 13:23'	System	05 Sep 2020 18:24:00
	System	05 Sep 2020 18:24:00

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 7'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:16:34', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '437a7c06-a7cf-46fa-996c-89ab81ccb4c1' User entered 'Yes (Y)'	System	06 Sep 2020 20:18:10
	System	06 Sep 2020 20:18:10

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:18:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '437a7c06-a7cf-46fa-996c-89ab81ccb4c1' User entered '99.1'	System	06 Sep 2020 20:18:10
	System	06 Sep 2020 20:18:10

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:18:03', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '437a7c06-a7cf-46fa-996c-89ab81ccb4c1' User entered 'No (N)'	System	06 Sep 2020 20:18:10
	System	06 Sep 2020 20:18:10

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:18:07', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '437a7c06-a7cf-46fa-996c-89ab81ccb4c1' User entered '06 Sep 2020 15:18'	System	06 Sep 2020 20:18:10
	System	06 Sep 2020 20:18:10

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:34:45', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '6d31af3e-1841-4f61-a4db-0b0c2d554be2' User entered 'None (1)'	System	31 Aug 2020 15:35:10
	System	31 Aug 2020 15:35:10

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:34:51', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '6d31af3e-1841-4f61-a4db-0b0c2d554be2' User entered 'No (N)'	System	31 Aug 2020 15:35:10
	System	31 Aug 2020 15:35:10

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:35:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '6d31af3e-1841-4f61-a4db-0b0c2d554be2' User entered 'No (N)'	System	31 Aug 2020 15:35:10
	System	31 Aug 2020 15:35:10

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:35:06', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '6d31af3e-1841-4f61-a4db-0b0c2d554be2' User entered 'None (1)'	System	31 Aug 2020 15:35:10
	System	31 Aug 2020 15:35:10

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:35:09', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '6d31af3e-1841-4f61-a4db-0b0c2d554be2'	System	31 Aug 2020 15:35:10
User entered '31 Aug 2020 10:35'	System	31 Aug 2020 15:35:10

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '31 Aug 2020 10:24'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '31 Aug 2020 12:54'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:27:07', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5b6bd572-1c7b-4261-8643-e2151b79bb56'	System	31 Aug 2020 19:31:16
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 19:31:16

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:27:11', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5b6bd572-1c7b-4261-8643-e2151b79bb56'	System	31 Aug 2020 19:31:16
User entered 'No (N)'	System	31 Aug 2020 19:31:16

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:27:18', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5b6bd572-1c7b-4261-8643-e2151b79bb56'	System	31 Aug 2020 19:31:16
User entered 'No (N)'	System	31 Aug 2020 19:31:16

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:27:26', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5b6bd572-1c7b-4261-8643-e2151b79bb56'	System	31 Aug 2020 19:31:16
User entered 'None (1)'	System	31 Aug 2020 19:31:16

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:27:29', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5b6bd572-1c7b-4261-8643-e2151b79bb56'	System	31 Aug 2020 19:31:16
User entered '31 Aug 2020 14:27'	System	31 Aug 2020 19:31:16

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '31 Aug 2020 13:49'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 2'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:30:49', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '57812d4a-b95e-43ea-b105-3cc2f9febcb1'	System	01 Sep 2020 17:31:10
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 17:31:10

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:30:52', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '57812d4a-b95e-43ea-b105-3cc2f9febcb1' User entered 'No (N)'	System	01 Sep 2020 17:31:10
	System	01 Sep 2020 17:31:10

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:30:56', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '57812d4a-b95e-43ea-b105-3cc2f9febcb1' User entered 'No (N)'	System	01 Sep 2020 17:31:10
	System	01 Sep 2020 17:31:10

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:31:03', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '57812d4a-b95e-43ea-b105-3cc2f9febcb1'	System	01 Sep 2020 17:31:10
User entered 'None (1)'	System	01 Sep 2020 17:31:10

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:31:05', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '57812d4a-b95e-43ea-b105-3cc2f9febcb1' User entered '01 Sep 2020 12:31'	System	01 Sep 2020 17:31:10
	System	01 Sep 2020 17:31:10

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 3'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:59:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f30c173b-eedb-476b-8505-96517a5c2d16'	System	02 Sep 2020 17:59:18
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 17:59:18

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:59:07', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f30c173b-eedb-476b-8505-96517a5c2d16' User entered 'No (N)'	System	02 Sep 2020 17:59:18
	System	02 Sep 2020 17:59:18

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:59:10', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f30c173b-ee4b-476b-8505-96517a5c2d16'	System	02 Sep 2020 17:59:18
User entered 'No (N)'	System	02 Sep 2020 17:59:18

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:59:15', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f30c173b-eedb-476b-8505-96517a5c2d16' User entered 'None (1)'	System	02 Sep 2020 17:59:18
	System	02 Sep 2020 17:59:18

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:59:17', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f30c173b-eedb-476b-8505-96517a5c2d16' User entered '02 Sep 2020 12:59'	System	02 Sep 2020 17:59:18
	System	02 Sep 2020 17:59:18

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 4'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:04:17', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2d6f3960-6e95-42b1-8cb2-040ff4c1dd16'	System	03 Sep 2020 18:04:36
User entered 'None (1)'	System	03 Sep 2020 18:04:36

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:04:20', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2d6f3960-6e95-42b1-8cb2-040ff4c1dd16'	System	03 Sep 2020 18:04:36
User entered 'No (N)'	System	03 Sep 2020 18:04:36

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:04:23', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2d6f3960-6e95-42b1-8cb2-040ff4c1dd16'	System	03 Sep 2020 18:04:36
User entered 'No (N)'	System	03 Sep 2020 18:04:36

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:04:27', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2d6f3960-6e95-42b1-8cb2-040ff4c1dd16'	System	03 Sep 2020 18:04:36
User entered 'None (1)'	System	03 Sep 2020 18:04:36

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:04:29', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2d6f3960-6e95-42b1-8cb2-040ff4c1dd16'	System	03 Sep 2020 18:04:36
User entered '03 Sep 2020 13:04'	System	03 Sep 2020 18:04:36

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 5'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:03:13', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '175a201e-c62d-4c6e-ac67-dc3b1a0cbc21' User entered 'None (1)'	System	04 Sep 2020 17:04:21
	System	04 Sep 2020 17:04:21

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:03:17', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '175a201e-c62d-4c6e-ac67-dc3b1a0cbc21' User entered 'No (N)'	System	04 Sep 2020 17:04:21
	System	04 Sep 2020 17:04:21

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:03:20', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '175a201e-c62d-4c6e-ac67-dc3b1a0cbc21' User entered 'No (N)'	System	04 Sep 2020 17:04:21
	System	04 Sep 2020 17:04:21

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:03:22', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '175a201e-c62d-4c6e-ac67-dc3b1a0cbc21' User entered 'None (1)'	System	04 Sep 2020 17:04:21
	System	04 Sep 2020 17:04:21

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:03:25', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '175a201e-c62d-4c6e-ac67-dc3b1a0cbc21' User entered '04 Sep 2020 12:03'	System	04 Sep 2020 17:04:21
	System	04 Sep 2020 17:04:21

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 6'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:22', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8093e692-e701-4a2d-8bdd-564198a9c67c' User entered 'None (1)'	System	05 Sep 2020 18:23:35
	System	05 Sep 2020 18:23:35

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:25', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8093e692-e701-4a2d-8bdd-564198a9c67c' User entered 'No (N)'	System	05 Sep 2020 18:23:35
	System	05 Sep 2020 18:23:35

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:27', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8093e692-e701-4a2d-8bdd-564198a9c67c' User entered 'No (N)'	System	05 Sep 2020 18:23:35
	System	05 Sep 2020 18:23:35

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:29', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8093e692-e701-4a2d-8bdd-564198a9c67c' User entered 'None (1)'	System	05 Sep 2020 18:23:35
	System	05 Sep 2020 18:23:35

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:32', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8093e692-e701-4a2d-8bdd-564198a9c67c' User entered '05 Sep 2020 13:23'	System	05 Sep 2020 18:23:35
	System	05 Sep 2020 18:23:35

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 7'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:16:06', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f02d614f-1668-4f62-a16a-b199e2fb6a9e'	System	06 Sep 2020 20:16:23
User entered 'None (1)'	System	06 Sep 2020 20:16:23

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:16:09', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f02d614f-1668-4f62-a16a-b199e2fb6a9e' User entered 'No (N)'	System	06 Sep 2020 20:16:23
	System	06 Sep 2020 20:16:23

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:16:12', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f02d614f-1668-4f62-a16a-b199e2fb6a9e'	System	06 Sep 2020 20:16:23
User entered 'No (N)'	System	06 Sep 2020 20:16:23

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:16:14', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f02d614f-1668-4f62-a16a-b199e2fb6a9e'	System	06 Sep 2020 20:16:23
User entered 'None (1)'	System	06 Sep 2020 20:16:23

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:16:18', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f02d614f-1668-4f62-a16a-b199e2fb6a9e' User entered '06 Sep 2020 15:16'	System	06 Sep 2020 20:16:23
	System	06 Sep 2020 20:16:23

US3392120

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:35:21', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2d884b54-8540-41ec-9718-c706a97c5a5e' User entered 'None (0)'	System	31 Aug 2020 15:35:47
	System	31 Aug 2020 15:35:47

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:35:23', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2d884b54-8540-41ec-9718-c706a97c5a5e' User entered 'None (0)'	System	31 Aug 2020 15:35:47
	System	31 Aug 2020 15:35:47

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:35:26', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2d884b54-8540-41ec-9718-c706a97c5a5e' User entered 'None (0)'	System	31 Aug 2020 15:35:47
	System	31 Aug 2020 15:35:47

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:35:29', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2d884b54-8540-41ec-9718-c706a97c5a5e' User entered 'None (0)'	System	31 Aug 2020 15:35:47
	System	31 Aug 2020 15:35:47

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:35:31', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2d884b54-8540-41ec-9718-c706a97c5a5e' User entered 'None (0)'	System	31 Aug 2020 15:35:47
	System	31 Aug 2020 15:35:47

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:35:34', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2d884b54-8540-41ec-9718-c706a97c5a5e' User entered 'None (0)'	System	31 Aug 2020 15:35:47
	System	31 Aug 2020 15:35:47

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:35:41', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2d884b54-8540-41ec-9718-c706a97c5a5e' User entered 'No (N)'	System	31 Aug 2020 15:35:47
	System	31 Aug 2020 15:35:47

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T10:35:44', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2d884b54-8540-41ec-9718-c706a97c5a5e' User entered '31 Aug 2020 10:35'	System	31 Aug 2020 15:35:47
	System	31 Aug 2020 15:35:47

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '31 Aug 2020 10:24'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '31 Aug 2020 12:54'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:26:22', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4db237a7-2d20-42d7-929e-2f02bea58ec9' User entered 'None (0)'	System	31 Aug 2020 19:30:55
	System	31 Aug 2020 19:30:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:26:25', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4db237a7-2d20-42d7-929e-2f02bea58ec9' User entered 'None (0)'	System	31 Aug 2020 19:30:55
	System	31 Aug 2020 19:30:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:26:30', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4db237a7-2d20-42d7-929e-2f02bea58ec9' User entered 'None (0)'	System	31 Aug 2020 19:30:55
	System	31 Aug 2020 19:30:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:26:34', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4db237a7-2d20-42d7-929e-2f02bea58ec9' User entered 'None (0)'	System	31 Aug 2020 19:30:55
	System	31 Aug 2020 19:30:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:26:36', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4db237a7-2d20-42d7-929e-2f02bea58ec9' User entered 'None (0)'	System	31 Aug 2020 19:30:55
	System	31 Aug 2020 19:30:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:26:40', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4db237a7-2d20-42d7-929e-2f02bea58ec9' User entered 'None (0)'	System	31 Aug 2020 19:30:55
	System	31 Aug 2020 19:30:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:26:45', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4db237a7-2d20-42d7-929e-2f02bea58ec9'	System	31 Aug 2020 19:30:55
User entered 'No (N)'	System	31 Aug 2020 19:30:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-08-31T14:26:50', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4db237a7-2d20-42d7-929e-2f02bea58ec9'	System	31 Aug 2020 19:30:55
User entered '31 Aug 2020 14:26'	System	31 Aug 2020 19:30:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '31 Aug 2020 13:49'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 2'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:31:12', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ece0e1ec-6442-4b4d-8875-93f342608d62' User entered 'None (0)'	System	01 Sep 2020 17:31:37
	System	01 Sep 2020 17:31:37

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:31:15', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ece0e1ec-6442-4b4d-8875-93f342608d62' User entered 'None (0)'	System	01 Sep 2020 17:31:37
	System	01 Sep 2020 17:31:37

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:31:18', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ece0e1ec-6442-4b4d-8875-93f342608d62' User entered 'None (0)'	System	01 Sep 2020 17:31:37
	System	01 Sep 2020 17:31:37

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:31:21', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ece0e1ec-6442-4b4d-8875-93f342608d62' User entered 'None (0)'	System	01 Sep 2020 17:31:37
	System	01 Sep 2020 17:31:37

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:31:25', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ece0e1ec-6442-4b4d-8875-93f342608d62' User entered 'None (0)'	System	01 Sep 2020 17:31:37
	System	01 Sep 2020 17:31:37

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:31:27', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ece0e1ec-6442-4b4d-8875-93f342608d62'	System	01 Sep 2020 17:31:37
User entered 'None (0)'	System	01 Sep 2020 17:31:37

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:31:32', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ece0e1ec-6442-4b4d-8875-93f342608d62' User entered 'No (N)'	System	01 Sep 2020 17:31:37
	System	01 Sep 2020 17:31:37

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-01T12:31:35', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ece0e1ec-6442-4b4d-8875-93f342608d62'	System	01 Sep 2020 17:31:37
User entered '01 Sep 2020 12:31'	System	01 Sep 2020 17:31:37

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 3'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:59:21', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4f243dbd-06c1-4989-948b-8562936ef962'	System	02 Sep 2020 17:59:39
User entered 'None (0)'	System	02 Sep 2020 17:59:39

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:59:23', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4f243dbd-06c1-4989-948b-8562936ef962'	System	02 Sep 2020 17:59:39
User entered 'None (0)'	System	02 Sep 2020 17:59:39

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:59:25', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4f243dbd-06c1-4989-948b-8562936ef962' User entered 'None (0)'	System	02 Sep 2020 17:59:39
	System	02 Sep 2020 17:59:39

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:59:27', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4f243dbd-06c1-4989-948b-8562936ef962' User entered 'None (0)'	System	02 Sep 2020 17:59:39
	System	02 Sep 2020 17:59:39

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:59:29', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4f243dbd-06c1-4989-948b-8562936ef962' User entered 'None (0)'	System	02 Sep 2020 17:59:39
	System	02 Sep 2020 17:59:39

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:59:32', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4f243dbd-06c1-4989-948b-8562936ef962'	System	02 Sep 2020 17:59:39
User entered 'None (0)'	System	02 Sep 2020 17:59:39

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:59:35', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4f243dbd-06c1-4989-948b-8562936ef962'	System	02 Sep 2020 17:59:39
User entered 'No (N)'	System	02 Sep 2020 17:59:39

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-02T12:59:37', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4f243dbd-06c1-4989-948b-8562936ef962'	System	02 Sep 2020 17:59:39
User entered '02 Sep 2020 12:59'	System	02 Sep 2020 17:59:39

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 4'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:04:40', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ba07fede-325c-44b8-9b71-a8c7b2e9180b' User entered 'None (0)'	System	03 Sep 2020 18:05:00
	System	03 Sep 2020 18:05:00

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:04:44', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ba07fede-325c-44b8-9b71-a8c7b2e9180b' User entered 'None (0)'	System	03 Sep 2020 18:05:00
	System	03 Sep 2020 18:05:00

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:04:46', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ba07fede-325c-44b8-9b71-a8c7b2e9180b' User entered 'None (0)'	System	03 Sep 2020 18:05:00
	System	03 Sep 2020 18:05:00

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:04:49', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ba07fede-325c-44b8-9b71-a8c7b2e9180b' User entered 'None (0)'	System	03 Sep 2020 18:05:00
	System	03 Sep 2020 18:05:00

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:04:51', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ba07fede-325c-44b8-9b71-a8c7b2e9180b' User entered 'None (0)'	System	03 Sep 2020 18:05:00
	System	03 Sep 2020 18:05:00

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:04:53', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ba07fede-325c-44b8-9b71-a8c7b2e9180b' User entered 'None (0)'	System	03 Sep 2020 18:05:00
	System	03 Sep 2020 18:05:00

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:04:56', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ba07fede-325c-44b8-9b71-a8c7b2e9180b' User entered 'No (N)'	System	03 Sep 2020 18:05:00
	System	03 Sep 2020 18:05:00

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-03T13:04:59', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ba07fede-325c-44b8-9b71-a8c7b2e9180b' User entered '03 Sep 2020 13:04'	System	03 Sep 2020 18:05:00
	System	03 Sep 2020 18:05:00

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 5'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:02:42', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '87d342d2-c378-4e82-88ff-ae716f8e8b' User entered 'None (0)'	System	04 Sep 2020 17:04:12
	System	04 Sep 2020 17:04:12

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:02:44', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '87d342d2-c378-4e82-88ff-ae716f8e8b' User entered 'None (0)'	System	04 Sep 2020 17:04:12
	System	04 Sep 2020 17:04:12

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:02:46', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '87d342d2-c378-4e82-88ff-ae716f8e8b' User entered 'None (0)'	System	04 Sep 2020 17:04:12
	System	04 Sep 2020 17:04:12

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:02:49', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '87d342d2-c378-4e82-88ff-ae716f8e8b' User entered 'None (0)'	System	04 Sep 2020 17:04:12
	System	04 Sep 2020 17:04:12

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:02:57', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '87d342d2-c378-4e82-88ff-ae716f8e8b' User entered 'None (0)'	System	04 Sep 2020 17:04:12
	System	04 Sep 2020 17:04:12

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:03:01', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '87d342d2-c378-4e82-88ff-ae716f8e8b' User entered 'None (0)'	System	04 Sep 2020 17:04:12
	System	04 Sep 2020 17:04:12

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:03:05', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '87d342d2-c378-4e82-88ff-ae716f8e8b' User entered 'No (N)'	System	04 Sep 2020 17:04:12
	System	04 Sep 2020 17:04:12

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-04T12:03:08', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '87d342d2-c378-4e82-88ff-ae716f8e8b' User entered '04 Sep 2020 12:03'	System	04 Sep 2020 17:04:12
	System	04 Sep 2020 17:04:12

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 6'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:02', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '920dd331-4b20-4cdd-88f7-acfcb08de728' User entered 'None (0)'	System	05 Sep 2020 18:23:24
	System	05 Sep 2020 18:23:24

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:04', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '920dd331-4b20-4cdd-88f7-acfcb08de728' User entered 'None (0)'	System	05 Sep 2020 18:23:24
	System	05 Sep 2020 18:23:24

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:06', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '920dd331-4b20-4cdd-88f7-acfcb08de728'	System	05 Sep 2020 18:23:24
User entered 'None (0)'	System	05 Sep 2020 18:23:24

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:08', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '920dd331-4b20-4cdd-88f7-acfcb08de728' User entered 'None (0)'	System	05 Sep 2020 18:23:24
	System	05 Sep 2020 18:23:24

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:10', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '920dd331-4b20-4cdd-88f7-acfcb08de728' User entered 'None (0)'	System	05 Sep 2020 18:23:24
	System	05 Sep 2020 18:23:24

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:13', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '920dd331-4b20-4cdd-88f7-acfcb08de728' User entered 'None (0)'	System	05 Sep 2020 18:23:24
	System	05 Sep 2020 18:23:24

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:17', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '920dd331-4b20-4cdd-88f7-acfcb08de728'	System	05 Sep 2020 18:23:24
User entered 'No (N)'	System	05 Sep 2020 18:23:24

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-05T13:23:19', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '920dd331-4b20-4cdd-88f7-acfcb08de728' User entered '05 Sep 2020 13:23'	System	05 Sep 2020 18:23:24
	System	05 Sep 2020 18:23:24

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 7'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:15:38', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '9c200ae1-d724-470f-b425-6cfcbb816805' User entered 'None (0)'	System	06 Sep 2020 20:16:07
	System	06 Sep 2020 20:16:07

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:15:41', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '9c200ae1-d724-470f-b425-6cfcbb816805' User entered 'None (0)'	System	06 Sep 2020 20:16:07
	System	06 Sep 2020 20:16:07

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:15:45', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '9c200ae1-d724-470f-b425-6cfcbb816805' User entered 'None (0)'	System	06 Sep 2020 20:16:07
	System	06 Sep 2020 20:16:07

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:15:48', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '9c200ae1-d724-470f-b425-6cfcbb816805' User entered 'None (0)'	System	06 Sep 2020 20:16:07
	System	06 Sep 2020 20:16:07

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:15:55', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '9c200ae1-d724-470f-b425-6cfcbb816805'	System	06 Sep 2020 20:16:07
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	06 Sep 2020 20:16:07

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:15:58', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '9c200ae1-d724-470f-b425-6cfcbb816805' User entered 'None (0)'	System	06 Sep 2020 20:16:07
	System	06 Sep 2020 20:16:07

US3392120

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:16:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '9c200ae1-d724-470f-b425-6cfcbb816805' User entered 'No (N)'	System	06 Sep 2020 20:16:07
	System	06 Sep 2020 20:16:07

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-06T15:16:03', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '9c200ae1-d724-470f-b425-6cfcbb816805'	System	06 Sep 2020 20:16:07
User entered '06 Sep 2020 15:16'	System	06 Sep 2020 20:16:07

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:22:55

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	06 Sep 2020 20:16:07
User entered 'Day 8'	System	06 Sep 2020 20:16:07

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 09 Jun 2021 17:25:38**

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-07T12:34:43', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '3e921670-8466-4264-aef8-68a5b01d7cdb' User entered 'None (0)'	System	07 Sep 2020 17:34:47
	System	07 Sep 2020 17:34:47

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-07T12:34:46', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '3e921670-8466-4264-aef8-68a5b01d7cdb' User entered '07 Sep 2020 12:34'	System	07 Sep 2020 17:34:47
	System	07 Sep 2020 17:34:47

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 20:16:07

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 20:16:07

US3392120

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	06 Sep 2020 20:16:07
User entered 'Day 8'	System	06 Sep 2020 20:16:07

US3392120

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-07T12:34:55', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '7e58bb76-ba5b-4511-8ed7-b4eda1815faf' User entered 'No (N)'	System	07 Sep 2020 17:35:04
	System	07 Sep 2020 17:35:04

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-07T12:35:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '7e58bb76-ba5b-4511-8ed7-b4eda1815faf' User entered '07 Sep 2020 12:35'	System	07 Sep 2020 17:35:04
	System	07 Sep 2020 17:35:04

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 20:16:07

**US3392120**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 20:16:07

US3392120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:05:23
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	30 Sep 2020 13:41:33

US3392120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:05:23
User entered '7 Sep 2020'	Brenda Lawson (b) (4)	30 Sep 2020 13:41:33

US3392120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:05:23
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	30 Sep 2020 13:41:33

US3392120

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:05:23
User entered empty.	Brenda Lawson (b) (4)	30 Sep 2020 13:41:33

US3392120

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:05:23
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	30 Sep 2020 13:41:37

US3392120

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'I'	System	30 Sep 2020 13:41:37

**US3392120**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:32:01
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	30 Sep 2020 13:41:56

US3392120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:32:01
User entered '16 Sep 2020'	Brenda Lawson (b) (4)	30 Sep 2020 13:41:56

US3392120

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:32:01
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	30 Sep 2020 13:41:56

**US3392120**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:32:01
User entered empty.	Brenda Lawson (b) (4)	30 Sep 2020 13:41:56

US3392120

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:32:01
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	30 Sep 2020 13:42:01

**US3392120**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:54:34
User entered 'I'	System	30 Sep 2020 13:42:01

**US3392120**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:12:34
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	30 Sep 2020 13:42:22

US3392120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:12:34
User closed query 'Per GCL Lab Recon: GCL has a swab sample with date of 22SEP2020 and a SARS-CoV-2 sample with date of 22SEP2020; however, there are no Covid Assessment nor Illness Visit completed. Please reconcile or clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 10:44:05
Query 'Per GCL Lab Recon: GCL has a swab sample with date of 22SEP2020 and a SARS-CoV-2 sample with date of 22SEP2020; however, there are no Covid Assessment nor Illness Visit completed. Please reconcile or clarify' answered with 'ILLNESS VISIT 22 SEPT COMPLETED' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 18:44:12
User opened query 'Per GCL Lab Recon: GCL has a swab sample with date of 22SEP2020 and a SARS-CoV-2 sample with date of 22SEP2020; however, there are no Covid Assessment nor Illness Visit completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 15:14:28
User entered '21 Sep 2020'	Brenda Lawson (b) (4) (b) (4)	30 Sep 2020 13:42:22

US3392120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:12:34
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	30 Sep 2020 13:42:22

US3392120

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:12:34
User entered empty.	Brenda Lawson (b) (4)	30 Sep 2020 13:42:22

US3392120

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:12:34
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	30 Sep 2020 13:42:26

**US3392120**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'I'	System	30 Sep 2020 13:42:26

US3392120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	30 Sep 2020 13:42:44

US3392120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '30 Sep 2020'	Brenda Lawson (b) (4)	30 Sep 2020 13:42:44

US3392120

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered 'Home (Home)'	Brenda Lawson (b) (4)	30 Sep 2020 13:42:44

**US3392120**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'VISIT2'	System	30 Sep 2020 13:42:44

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '08:06'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

**US3392120**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered '30 Sep 2020 08:06'	System	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

**US3392120**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:25:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '64'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'bpm'	System	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '14'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'breaths/min'	System	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '124'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'mmHg'	System	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '70'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'mmHg'	System	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '09:31'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

**US3392120**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered '30 Sep 2020 09:31'	System	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '66'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'bpm'	System	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '14'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'breaths/min'	System	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '120'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'mmHg'	System	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '70'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'mmHg'	System	31 Oct 2020 17:59:36

US3392120

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	30 Sep 2020 13:42:55

US3392120

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '30 Sep 2020'	Brenda Lawson (b) (4)	30 Sep 2020 13:42:55

US3392120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	30 Sep 2020 14:05:10

US3392120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered empty.	Brenda Lawson (b) (4)	30 Sep 2020 14:05:10

US3392120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

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)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered empty.	Brenda Lawson (b) (4)	30 Sep 2020 14:05:10

**US3392120**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:25:38**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 14:05:10

US3392120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '30 Sep 2020'	Brenda Lawson (b) (4)	30 Sep 2020 14:05:10

US3392120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '08:52'	Brenda Lawson (b) (4)	30 Sep 2020 14:05:10

**US3392120**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered '30 Sep 2020 08:52'	System	30 Sep 2020 14:05:10

US3392120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:41:11
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'PATIENT REQUESTED RT ARM FOR INJECTION' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 15:51:34
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	30 Sep 2020 14:05:10
User entered 'Right Arm (RIGHT ARM)'	Brenda Lawson (b) (4) (b) (4)	30 Sep 2020 14:05:10

US3392120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'ONCE'	System	30 Sep 2020 14:05:10

US3392120

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 14:05:10

US3392120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	30 Sep 2020 13:43:48

US3392120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:59:32
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'V3 was completed on 02Nov. updated' (Site from DM).	Heather Salisbury (b) (4) (b) (4)	16 Nov 2020 20:14:06
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 22:03:55
User entered '30 Sep 2020'	Brenda Lawson (b) (4) (b) (4)	30 Sep 2020 13:43:48

US3392120

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Sep 2020 13:44:00
User entered '08:30' reason for change: Data Entry Error	System	30 Sep 2020 13:44:00
User opened query 'Data is required. Please provide.' (Site from System).	Brenda Lawson (b) (4)	30 Sep 2020 13:43:48
User entered empty.	(b) (4)	30 Sep 2020 13:43:48

**US3392120**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered '30 Sep 2020 08:30'	System	30 Sep 2020 13:44:00
User entered empty.	System	30 Sep 2020 13:43:48

US3392120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:25:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '30 Sep 2020'	Brenda Lawson (b) (4)	30 Sep 2020 13:43:16

US3392120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Lawson (b) (4)	30 Sep 2020 13:43:16

US3392120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	30 Sep 2020 13:43:16

**US3392120**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered '08:25'	Brenda Lawson (b) (4)	30 Sep 2020 13:43:16

**US3392120**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered '30 Sep 2020 08:25'	System	30 Sep 2020 13:43:16

US3392120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Lawson (b) (4)	30 Sep 2020 13:43:16

US3392120

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered 'No (N)'	Brenda Lawson (b) (4)	30 Sep 2020 13:43:16

**US3392120**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User entered empty.	Brenda Lawson (b) (4)	30 Sep 2020 13:43:16

**US3392120**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered empty.	System	30 Sep 2020 13:43:16

US3392120

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:50:28
User closed query 'Per GCL Lab Reconciliation Re-query: SWAB: Previous response is noted, however, please initiate COVID Diagnostic Test Form and update the swab sample data for the corresponding date 22Sep2020. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 04:51:05
Query 'Per GCL Lab Reconciliation Re-query: SWAB: Previous response is noted, however, please initiate COVID Diagnostic Test Form and update the swab sample data for the corresponding date 22Sep2020. Thank you.' answered with 'DATA UPDATED. DATA ENTRY ERROR.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 22:28:05
User opened query 'Per GCL Lab Reconciliation Re-query: SWAB: Previous response is noted, however, please initiate COVID Diagnostic Test Form and update the swab sample data for the corresponding date 22Sep2020. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:48:05
User closed query 'Per GCL Lab Reconciliation Re-query: SWAB: Response noted. However, data is not yet entered in EDC. Please complete the covid diagnostic test under covid-19 assessment folder.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:48:05
Query 'Per GCL Lab Reconciliation Re-query: SWAB: Response noted. However, data is not yet entered in EDC. Please complete the covid diagnostic test under covid-19 assessment folder.' answered with 'updated' (Site from DM).	Heather Salisbury (b) (4) (b) (4)	08 Dec 2020 21:49:33
User opened query 'Per GCL Lab Reconciliation Re-query: SWAB: Response noted. However, data is not yet entered in EDC. Please complete the covid diagnostic test under covid-19 assessment folder.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 08:51:53

US3392120

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation Re-query: Query response noted. However, COVID diagnostic test dated 22Sep2020 is not yet reported in EDC. Please enter the details under the appropriate form. Else clarify.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 08:51:53
Query 'Per GCL Lab Reconciliation Re-query: Query response noted. However, COVID diagnostic test dated 22Sep2020 is not yet reported in EDC. Please enter the details under the appropriate form. Else clarify.' answered with 'DATA WAS ENTERED' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 18:47:10
User opened query 'Per GCL Lab Reconciliation Re-query: Query response noted. However, COVID diagnostic test dated 22Sep2020 is not yet reported in EDC. Please enter the details under the appropriate form. Else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:38:28
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 22Sep2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:38:28
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 22Sep2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'COLVID ILLNESS VISIT 1 ECRF GENERATED AND DATA UPDATED.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 18:08:31
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 22Sep2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:03:15
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	30 Sep 2020 13:43:20

US3392120

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'I'	System	30 Sep 2020 13:43:20

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:19:35', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '79db7508-7070-409a-a149-e089c3e64ab7' User entered 'Yes (Y)'	System	30 Sep 2020 14:19:56
	System	30 Sep 2020 14:19:56

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:19:41', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '79db7508-7070-409a-a149-e089c3e64ab7' User entered '98.4'	System	30 Sep 2020 14:19:56
	System	30 Sep 2020 14:19:56

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:19:51', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '79db7508-7070-409a-a149-e089c3e64ab7'	System	30 Sep 2020 14:19:56
User entered 'No (N)'	System	30 Sep 2020 14:19:56

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:19:55', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '79db7508-7070-409a-a149-e089c3e64ab7' User entered '30 Sep 2020 09:19'	System	30 Sep 2020 14:19:56
	System	30 Sep 2020 14:19:56

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '30 Sep 2020 09:12'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '30 Sep 2020 11:42'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:37:39', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '46e9dd37-59d3-4142-8962-53be6b9f9fb2'	System	30 Sep 2020 23:37:57
User entered 'Yes (Y)'	System	30 Sep 2020 23:37:57

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:37:46', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '46e9dd37-59d3-4142-8962-53be6b9f9fb2' User entered '98.4'	System	30 Sep 2020 23:37:57
	System	30 Sep 2020 23:37:57

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:37:50', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '46e9dd37-59d3-4142-8962-53be6b9f9fb2'	System	30 Sep 2020 23:37:57
User entered 'No (N)'	System	30 Sep 2020 23:37:57

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:37:53', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '46e9dd37-59d3-4142-8962-53be6b9f9fb2'	System	30 Sep 2020 23:37:57
User entered '30 Sep 2020 18:37'	System	30 Sep 2020 23:37:57

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '30 Sep 2020 12:37'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 2'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:25:15', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'c3fa3122-9ae0-4b4d-acc5-ef7bafa38cc6' User entered 'Yes (Y)'	System	01 Oct 2020 18:25:43
	System	01 Oct 2020 18:25:43

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:25:28', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'c3fa3122-9ae0-4b4d-acc5-ef7bafa38cc6' User entered '99.1'	System	01 Oct 2020 18:25:43
	System	01 Oct 2020 18:25:43

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:25:35', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'c3fa3122-9ae0-4b4d-acc5-ef7bafa38cc6' User entered 'No (N)'	System	01 Oct 2020 18:25:43
	System	01 Oct 2020 18:25:43

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:25:40', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'c3fa3122-9ae0-4b4d-acc5-ef7bafa38cc6'	System	01 Oct 2020 18:25:43
User entered '01 Oct 2020 13:25'	System	01 Oct 2020 18:25:43

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 3'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:33:42', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '7748400f-341f-47c9-bf58-ed8e465d15c2'	System	02 Oct 2020 17:34:12
User entered 'Yes (Y)'	System	02 Oct 2020 17:34:12

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:33:59', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '7748400f-341f-47c9-bf58-ed8e465d15c2'	System	02 Oct 2020 17:34:12
User entered '97.8'	System	02 Oct 2020 17:34:12

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:34:03', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '7748400f-341f-47c9-bf58-ed8e465d15c2'	System	02 Oct 2020 17:34:12
User entered 'No (N)'	System	02 Oct 2020 17:34:12

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:34:07', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '7748400f-341f-47c9-bf58-ed8e465d15c2'	System	02 Oct 2020 17:34:12
User entered '02 Oct 2020 12:34'	System	02 Oct 2020 17:34:12

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 4'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:30:42', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '1f6ab06a-1afd-4985-8141-76725ac3ceal' User entered 'Yes (Y)'	System	03 Oct 2020 20:32:05
	System	03 Oct 2020 20:32:05

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:31:55', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '1f6ab06a-1afd-4985-8141-76725ac3ceal' User entered '98.5'	System	03 Oct 2020 20:32:05
	System	03 Oct 2020 20:32:05

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:31:58', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '1f6ab06a-1afd-4985-8141-76725ac3ceal'	System	03 Oct 2020 20:32:05
User entered 'No (N)'	System	03 Oct 2020 20:32:05

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:32:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '1f6ab06a-1afd-4985-8141-76725ac3ceal' User entered '03 Oct 2020 15:32'	System	03 Oct 2020 20:32:05
	System	03 Oct 2020 20:32:05

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 5'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:37:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2e55465c-6b2a-4cb4-bf18-328c64c38e00' User entered 'Yes (Y)'	System	04 Oct 2020 20:38:31
	System	04 Oct 2020 20:38:31

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:38:23', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2e55465c-6b2a-4cb4-bf18-328c64c38e00' User entered '98.6'	System	04 Oct 2020 20:38:31
	System	04 Oct 2020 20:38:31

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:38:27', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2e55465c-6b2a-4cb4-bf18-328c64c38e00'	System	04 Oct 2020 20:38:31
User entered 'No (N)'	System	04 Oct 2020 20:38:31

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:38:29', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2e55465c-6b2a-4cb4-bf18-328c64c38e00' User entered '04 Oct 2020 15:38'	System	04 Oct 2020 20:38:31
	System	04 Oct 2020 20:38:31

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 6'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:53:30', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8b1928a0-003e-4539-944c-4661cc2781c6' User entered 'Yes (Y)'	System	05 Oct 2020 17:53:46
	System	05 Oct 2020 17:53:46

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:53:36', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8b1928a0-003e-4539-944c-4661cc2781c6' User entered '98.3'	System	05 Oct 2020 17:53:46
	System	05 Oct 2020 17:53:46

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:53:40', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8b1928a0-003e-4539-944c-4661cc2781c6'	System	05 Oct 2020 17:53:46
User entered 'No (N)'	System	05 Oct 2020 17:53:46

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:53:44', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8b1928a0-003e-4539-944c-4661cc2781c6' User entered '05 Oct 2020 12:53'	System	05 Oct 2020 17:53:46
	System	05 Oct 2020 17:53:46

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 7'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:24:38', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'd087f94d-47b1-4b4b-8392-c50d9129563c' User entered 'Yes (Y)'	System	06 Oct 2020 20:26:27
	System	06 Oct 2020 20:26:27

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:26:18', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'd087f94d-47b1-4b4b-8392-c50d9129563c' User entered '97.9'	System	06 Oct 2020 20:26:27
	System	06 Oct 2020 20:26:27

US3392120

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:26:21', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'd087f94d-47b1-4b4b-8392-c50d9129563c' User entered 'No (N)'	System	06 Oct 2020 20:26:27
	System	06 Oct 2020 20:26:27

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:26:23', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'd087f94d-47b1-4b4b-8392-c50d9129563c' User entered '06 Oct 2020 15:26'	System	06 Oct 2020 20:26:27
	System	06 Oct 2020 20:26:27

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:20:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '450c16f8-583e-4485-b200-056e472a9347'	System	30 Sep 2020 14:20:38
User entered 'None (1)'	System	30 Sep 2020 14:20:38

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:20:14', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '450c16f8-583e-4485-b200-056e472a9347'	System	30 Sep 2020 14:20:38
User entered 'No (N)'	System	30 Sep 2020 14:20:38

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:20:26', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '450c16f8-583e-4485-b200-056e472a9347'	System	30 Sep 2020 14:20:38
User entered 'No (N)'	System	30 Sep 2020 14:20:38

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:20:32', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '450c16f8-583e-4485-b200-056e472a9347'	System	30 Sep 2020 14:20:38
User entered 'None (1)'	System	30 Sep 2020 14:20:38

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:20:35', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '450c16f8-583e-4485-b200-056e472a9347' User entered '30 Sep 2020 09:20'	System	30 Sep 2020 14:20:38
	System	30 Sep 2020 14:20:38

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '30 Sep 2020 09:12'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '30 Sep 2020 11:42'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:37:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2b6d62b4-7929-4467-ba9a-63882ff3f9d1'	System	30 Sep 2020 23:37:34
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 23:37:34

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:37:14', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2b6d62b4-7929-4467-ba9a-63882ff3f9d1' User entered 'No (N)'	System	30 Sep 2020 23:37:34
	System	30 Sep 2020 23:37:34

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:37:20', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2b6d62b4-7929-4467-ba9a-63882ff3f9d1' User entered 'No (N)'	System	30 Sep 2020 23:37:34
	System	30 Sep 2020 23:37:34

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:37:29', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2b6d62b4-7929-4467-ba9a-63882ff3f9d1' User entered 'None (1)'	System	30 Sep 2020 23:37:34
	System	30 Sep 2020 23:37:34

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:37:31', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '2b6d62b4-7929-4467-ba9a-63882ff3f9d1' User entered '30 Sep 2020 18:37'	System	30 Sep 2020 23:37:34
	System	30 Sep 2020 23:37:34

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '30 Sep 2020 12:37'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 2'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:24:56', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5aa2f3aa-b5fa-4a03-a777-18e0cce787e1'	System	01 Oct 2020 18:25:12
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 18:25:12

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:25:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5aa2f3aa-b5fa-4a03-a777-18e0cce787e1' User entered 'No (N)'	System	01 Oct 2020 18:25:12
	System	01 Oct 2020 18:25:12

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:25:03', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5aa2f3aa-b5fa-4a03-a777-18e0cce787e1' User entered 'No (N)'	System	01 Oct 2020 18:25:12
	System	01 Oct 2020 18:25:12

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:25:05', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5aa2f3aa-b5fa-4a03-a777-18e0cce787e1' User entered 'None (1)'	System	01 Oct 2020 18:25:12
	System	01 Oct 2020 18:25:12

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:25:10', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5aa2f3aa-b5fa-4a03-a777-18e0cce787e1' User entered '01 Oct 2020 13:25'	System	01 Oct 2020 18:25:12
	System	01 Oct 2020 18:25:12

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 3'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:32:35', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '149098f7-e0e2-4d71-8298-924ceeb8e6d0'	System	02 Oct 2020 17:32:53
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 17:32:53

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:32:38', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '149098f7-e0e2-4d71-8298-924ceeb8e6d0' User entered 'No (N)'	System	02 Oct 2020 17:32:53
	System	02 Oct 2020 17:32:53

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:32:41', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '149098f7-e0e2-4d71-8298-924ceeb8e6d0' User entered 'No (N)'	System	02 Oct 2020 17:32:53
	System	02 Oct 2020 17:32:53

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:32:48', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '149098f7-e0e2-4d71-8298-924ceeb8e6d0'	System	02 Oct 2020 17:32:53
User entered 'None (1)'	System	02 Oct 2020 17:32:53

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:32:50', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '149098f7-e0e2-4d71-8298-924ceeb8e6d0' User entered '02 Oct 2020 12:32'	System	02 Oct 2020 17:32:53
	System	02 Oct 2020 17:32:53

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 4'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:30:25', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'b5fc6f49-9172-4ec2-8bab-c5d3e61e2639'	System	03 Oct 2020 20:30:40
User entered 'None (1)'	System	03 Oct 2020 20:30:40

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:30:28', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'b5fc6f49-9172-4ec2-8bab-c5d3e61e2639'	System	03 Oct 2020 20:30:40
User entered 'No (N)'	System	03 Oct 2020 20:30:40

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:30:31', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'b5fc6f49-9172-4ec2-8bab-c5d3e61e2639'	System	03 Oct 2020 20:30:40
User entered 'No (N)'	System	03 Oct 2020 20:30:40

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:30:34', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'b5fc6f49-9172-4ec2-8bab-c5d3e61e2639'	System	03 Oct 2020 20:30:40
User entered 'None (1)'	System	03 Oct 2020 20:30:40

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:30:36', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'b5fc6f49-9172-4ec2-8bab-c5d3e61e2639'	System	03 Oct 2020 20:30:40
User entered '03 Oct 2020 15:30'	System	03 Oct 2020 20:30:40

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 5'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:36:42', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '00a81009-6bdc-4d7b-811b-c0f3e0137567'	System	04 Oct 2020 20:36:55
User entered 'None (1)'	System	04 Oct 2020 20:36:55

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:36:44', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '00a81009-6bdc-4d7b-811b-c0f3e0137567' User entered 'No (N)'	System	04 Oct 2020 20:36:55
	System	04 Oct 2020 20:36:55

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:36:49', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '00a81009-6bdc-4d7b-811b-c0f3e0137567' User entered 'No (N)'	System	04 Oct 2020 20:36:55
	System	04 Oct 2020 20:36:55

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:36:50', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '00a81009-6bdc-4d7b-811b-c0f3e0137567'	System	04 Oct 2020 20:36:55
User entered 'None (1)'	System	04 Oct 2020 20:36:55

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:36:53', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '00a81009-6bdc-4d7b-811b-c0f3e0137567' User entered '04 Oct 2020 15:36'	System	04 Oct 2020 20:36:55
	System	04 Oct 2020 20:36:55

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 6'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:53:13', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f434cf7f-8895-4776-9319-00fcba8bd411'	System	05 Oct 2020 17:53:26
User entered 'None (1)'	System	05 Oct 2020 17:53:26

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:53:16', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f434cf7f-8895-4776-9319-00fcba8bd411'	System	05 Oct 2020 17:53:26
User entered 'No (N)'	System	05 Oct 2020 17:53:26

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:53:19', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f434cf7f-8895-4776-9319-00fcba8bd411'	System	05 Oct 2020 17:53:26
User entered 'No (N)'	System	05 Oct 2020 17:53:26

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:53:21', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f434cf7f-8895-4776-9319-00fcba8bd411'	System	05 Oct 2020 17:53:26
User entered 'None (1)'	System	05 Oct 2020 17:53:26

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:53:24', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f434cf7f-8895-4776-9319-00fcba8bd411' User entered '05 Oct 2020 12:53'	System	05 Oct 2020 17:53:26
	System	05 Oct 2020 17:53:26

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 7'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:24:22', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'a905e715-47f9-451b-95ab-ccc9b62b09b'	System	06 Oct 2020 20:25:23
User entered 'None (1)'	System	06 Oct 2020 20:25:23

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:24:24', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'a905e715-47f9-451b-95ab-cccf9b62b09b' User entered 'No (N)'	System	06 Oct 2020 20:25:23
	System	06 Oct 2020 20:25:23

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:24:26', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'a905e715-47f9-451b-95ab-cccf9b62b09b' User entered 'No (N)'	System	06 Oct 2020 20:25:23
	System	06 Oct 2020 20:25:23

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:24:29', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'a905e715-47f9-451b-95ab-ccc9b62b09b'	System	06 Oct 2020 20:25:23
User entered 'None (1)'	System	06 Oct 2020 20:25:23

US3392120

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:24:32', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'a905e715-47f9-451b-95ab-cccf9b62b09b' User entered '06 Oct 2020 15:24'	System	06 Oct 2020 20:25:23
	System	06 Oct 2020 20:25:23

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:20:39', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'e48864bb-a319-41a1-96f2-83d4ac307665' User entered 'None (0)'	System	30 Sep 2020 14:21:20
	System	30 Sep 2020 14:21:20

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:20:41', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'e48864bb-a319-41a1-96f2-83d4ac307665' User entered 'None (0)'	System	30 Sep 2020 14:21:20
	System	30 Sep 2020 14:21:20

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:20:44', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'e48864bb-a319-41a1-96f2-83d4ac307665' User entered 'None (0)'	System	30 Sep 2020 14:21:20
	System	30 Sep 2020 14:21:20

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:20:46', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'e48864bb-a319-41a1-96f2-83d4ac307665' User entered 'None (0)'	System	30 Sep 2020 14:21:20
	System	30 Sep 2020 14:21:20

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:20:49', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'e48864bb-a319-41a1-96f2-83d4ac307665' User entered 'None (0)'	System	30 Sep 2020 14:21:20
	System	30 Sep 2020 14:21:20

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:21:06', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'e48864bb-a319-41a1-96f2-83d4ac307665' User entered 'None (0)'	System	30 Sep 2020 14:21:20
	System	30 Sep 2020 14:21:20

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:21:14', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'e48864bb-a319-41a1-96f2-83d4ac307665' User entered 'No (N)'	System	30 Sep 2020 14:21:20
	System	30 Sep 2020 14:21:20

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T09:21:17', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'e48864bb-a319-41a1-96f2-83d4ac307665' User entered '30 Sep 2020 09:21'	System	30 Sep 2020 14:21:20
	System	30 Sep 2020 14:21:20

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '30 Sep 2020 09:12'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '30 Sep 2020 11:42'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:36:14', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '6ad32e22-db9a-4b43-ab0e-b01f8485e16a'	System	30 Sep 2020 23:36:50
User entered 'No interference with activity (1)'	System	30 Sep 2020 23:36:50

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:36:18', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '6ad32e22-db9a-4b43-ab0e-b01f8485e16a' User entered 'None (0)'	System	30 Sep 2020 23:36:50
	System	30 Sep 2020 23:36:50

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:36:24', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '6ad32e22-db9a-4b43-ab0e-b01f8485e16a' User entered 'None (0)'	System	30 Sep 2020 23:36:50
	System	30 Sep 2020 23:36:50

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:36:30', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '6ad32e22-db9a-4b43-ab0e-b01f8485e16a' User entered 'None (0)'	System	30 Sep 2020 23:36:50
	System	30 Sep 2020 23:36:50

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:36:35', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '6ad32e22-db9a-4b43-ab0e-b01f8485e16a'	System	30 Sep 2020 23:36:50
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	30 Sep 2020 23:36:50

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:36:38', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '6ad32e22-db9a-4b43-ab0e-b01f8485e16a' User entered 'None (0)'	System	30 Sep 2020 23:36:50
	System	30 Sep 2020 23:36:50

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:36:43', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '6ad32e22-db9a-4b43-ab0e-b01f8485e16a' User entered 'No (N)'	System	30 Sep 2020 23:36:50
	System	30 Sep 2020 23:36:50

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-09-30T18:36:48', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '6ad32e22-db9a-4b43-ab0e-b01f8485e16a' User entered '30 Sep 2020 18:36'	System	30 Sep 2020 23:36:50
	System	30 Sep 2020 23:36:50

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '30 Sep 2020 12:37'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 2'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:24:16', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f5e09bbe-f03f-4546-853e-872d62016499'	System	01 Oct 2020 18:24:51
User entered 'None (0)'	System	01 Oct 2020 18:24:51

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:24:19', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f5e09bbe-f03f-4546-853e-872d62016499'	System	01 Oct 2020 18:24:51
User entered 'None (0)'	System	01 Oct 2020 18:24:51

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:24:24', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f5e09bbe-f03f-4546-853e-872d62016499'	System	01 Oct 2020 18:24:51
User entered 'None (0)'	System	01 Oct 2020 18:24:51

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:24:28', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f5e09bbe-f03f-4546-853e-872d62016499' User entered 'None (0)'	System	01 Oct 2020 18:24:51
	System	01 Oct 2020 18:24:51

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:24:40', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f5e09bbe-f03f-4546-853e-872d62016499'	System	01 Oct 2020 18:24:51
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	01 Oct 2020 18:24:51

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:25:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:24:42', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f5e09bbe-f03f-4546-853e-872d62016499' User entered 'None (0)'	System	01 Oct 2020 18:24:51
	System	01 Oct 2020 18:24:51

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:24:45', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f5e09bbe-f03f-4546-853e-872d62016499'	System	01 Oct 2020 18:24:51
User entered 'No (N)'	System	01 Oct 2020 18:24:51

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-01T13:24:48', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'f5e09bbe-f03f-4546-853e-872d62016499'	System	01 Oct 2020 18:24:51
User entered '01 Oct 2020 13:24'	System	01 Oct 2020 18:24:51

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 3'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:32:57', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'd0098934-0753-4e1d-8378-d96367a851e5'	System	02 Oct 2020 17:33:40
User entered 'None (0)'	System	02 Oct 2020 17:33:40

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:33:05', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'd0098934-0753-4e1d-8378-d96367a851e5'	System	02 Oct 2020 17:33:40
User entered 'None (0)'	System	02 Oct 2020 17:33:40

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:33:13', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'd0098934-0753-4e1d-8378-d96367a851e5'	System	02 Oct 2020 17:33:40
User entered 'None (0)'	System	02 Oct 2020 17:33:40

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:33:16', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'd0098934-0753-4e1d-8378-d96367a851e5'	System	02 Oct 2020 17:33:40
User entered 'None (0)'	System	02 Oct 2020 17:33:40

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:33:19', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'd0098934-0753-4e1d-8378-d96367a851e5'	System	02 Oct 2020 17:33:40
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	02 Oct 2020 17:33:40

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:33:21', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'd0098934-0753-4e1d-8378-d96367a851e5'	System	02 Oct 2020 17:33:40
User entered 'None (0)'	System	02 Oct 2020 17:33:40

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:33:24', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'd0098934-0753-4e1d-8378-d96367a851e5'	System	02 Oct 2020 17:33:40
User entered 'No (N)'	System	02 Oct 2020 17:33:40

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-02T12:33:37', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'd0098934-0753-4e1d-8378-d96367a851e5'	System	02 Oct 2020 17:33:40
User entered '02 Oct 2020 12:33'	System	02 Oct 2020 17:33:40

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 4'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:30:01', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '80ea52c5-703f-486a-8637-e27e4129ffad' User entered 'None (0)'	System	03 Oct 2020 20:30:21
	System	03 Oct 2020 20:30:21

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:30:04', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '80ea52c5-703f-486a-8637-e27e4129ffad' User entered 'None (0)'	System	03 Oct 2020 20:30:21
	System	03 Oct 2020 20:30:21

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:30:06', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '80ea52c5-703f-486a-8637-e27e4129ffad' User entered 'None (0)'	System	03 Oct 2020 20:30:21
	System	03 Oct 2020 20:30:21

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:30:09', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '80ea52c5-703f-486a-8637-e27e4129ffad' User entered 'None (0)'	System	03 Oct 2020 20:30:21
	System	03 Oct 2020 20:30:21

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:30:11', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '80ea52c5-703f-486a-8637-e27e4129ffad' User entered 'None (0)'	System	03 Oct 2020 20:30:21
	System	03 Oct 2020 20:30:21

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:30:14', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '80ea52c5-703f-486a-8637-e27e4129ffad' User entered 'None (0)'	System	03 Oct 2020 20:30:21
	System	03 Oct 2020 20:30:21

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:30:16', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '80ea52c5-703f-486a-8637-e27e4129ffad'	System	03 Oct 2020 20:30:21
User entered 'No (N)'	System	03 Oct 2020 20:30:21

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-03T15:30:19', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '80ea52c5-703f-486a-8637-e27e4129ffad'	System	03 Oct 2020 20:30:21
User entered '03 Oct 2020 15:30'	System	03 Oct 2020 20:30:21

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 5'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:38:33', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '0294aa28-e36c-480e-9fa3-205edb6c5e1b' User entered 'None (0)'	System	04 Oct 2020 20:38:55
	System	04 Oct 2020 20:38:55

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:38:35', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '0294aa28-e36c-480e-9fa3-205edb6c5e1b' User entered 'None (0)'	System	04 Oct 2020 20:38:55
	System	04 Oct 2020 20:38:55

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:38:37', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '0294aa28-e36c-480e-9fa3-205edb6c5e1b' User entered 'None (0)'	System	04 Oct 2020 20:38:55
	System	04 Oct 2020 20:38:55

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:38:40', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '0294aa28-e36c-480e-9fa3-205edb6c5e1b' User entered 'None (0)'	System	04 Oct 2020 20:38:55
	System	04 Oct 2020 20:38:55

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:38:44', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '0294aa28-e36c-480e-9fa3-205edb6c5e1b' User entered 'None (0)'	System	04 Oct 2020 20:38:55
	System	04 Oct 2020 20:38:55

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:38:46', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '0294aa28-e36c-480e-9fa3-205edb6c5e1b' User entered 'None (0)'	System	04 Oct 2020 20:38:55
	System	04 Oct 2020 20:38:55

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:38:49', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '0294aa28-e36c-480e-9fa3-205edb6c5e1b' User entered 'No (N)'	System	04 Oct 2020 20:38:55
	System	04 Oct 2020 20:38:55

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-04T15:38:52', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '0294aa28-e36c-480e-9fa3-205edb6c5e1b' User entered '04 Oct 2020 15:38'	System	04 Oct 2020 20:38:55
	System	04 Oct 2020 20:38:55

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 6'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:52:55', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'df4a878e-ac47-4336-97b5-5de932a09b04' User entered 'None (0)'	System	05 Oct 2020 17:53:11
	System	05 Oct 2020 17:53:11

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:52:57', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'df4a878e-ac47-4336-97b5-5de932a09b04' User entered 'None (0)'	System	05 Oct 2020 17:53:11
	System	05 Oct 2020 17:53:11

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:52:59', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'df4a878e-ac47-4336-97b5-5de932a09b04' User entered 'None (0)'	System	05 Oct 2020 17:53:11
	System	05 Oct 2020 17:53:11

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:53:01', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'df4a878e-ac47-4336-97b5-5de932a09b04' User entered 'None (0)'	System	05 Oct 2020 17:53:11
	System	05 Oct 2020 17:53:11

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:53:03', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'df4a878e-ac47-4336-97b5-5de932a09b04' User entered 'None (0)'	System	05 Oct 2020 17:53:11
	System	05 Oct 2020 17:53:11

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:53:05', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'df4a878e-ac47-4336-97b5-5de932a09b04' User entered 'None (0)'	System	05 Oct 2020 17:53:11
	System	05 Oct 2020 17:53:11

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:53:07', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'df4a878e-ac47-4336-97b5-5de932a09b04' User entered 'No (N)'	System	05 Oct 2020 17:53:11
	System	05 Oct 2020 17:53:11

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-05T12:53:09', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'df4a878e-ac47-4336-97b5-5de932a09b04'	System	05 Oct 2020 17:53:11
User entered '05 Oct 2020 12:53'	System	05 Oct 2020 17:53:11

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	30 Sep 2020 14:05:10
User entered 'Day 7'	System	30 Sep 2020 14:05:10

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:24:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'bc77700a-0444-4dd0-a8a5-25da78e91de5' User entered 'None (0)'	System	06 Oct 2020 20:25:17
	System	06 Oct 2020 20:25:17

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:24:02', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'bc77700a-0444-4dd0-a8a5-25da78e91de5' User entered 'None (0)'	System	06 Oct 2020 20:25:17
	System	06 Oct 2020 20:25:17

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:24:04', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'bc77700a-0444-4dd0-a8a5-25da78e91de5' User entered 'None (0)'	System	06 Oct 2020 20:25:17
	System	06 Oct 2020 20:25:17

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:24:06', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'bc77700a-0444-4dd0-a8a5-25da78e91de5' User entered 'None (0)'	System	06 Oct 2020 20:25:17
	System	06 Oct 2020 20:25:17

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:24:08', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'bc77700a-0444-4dd0-a8a5-25da78e91de5' User entered 'None (0)'	System	06 Oct 2020 20:25:17
	System	06 Oct 2020 20:25:17

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:24:10', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'bc77700a-0444-4dd0-a8a5-25da78e91de5' User entered 'None (0)'	System	06 Oct 2020 20:25:17
	System	06 Oct 2020 20:25:17

US3392120

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:24:13', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'bc77700a-0444-4dd0-a8a5-25da78e91de5' User entered 'No (N)'	System	06 Oct 2020 20:25:17
	System	06 Oct 2020 20:25:17

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-06T15:24:18', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'bc77700a-0444-4dd0-a8a5-25da78e91de5' User entered '06 Oct 2020 15:24'	System	06 Oct 2020 20:25:17
	System	06 Oct 2020 20:25:17

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:25:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 14:05:10

**US3392120**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:56:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:16:21

US3392120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:56:10
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:16:21

US3392120

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:56:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:16:21

**US3392120**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:56:10
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 17:16:21

US3392120

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:56:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 17:16:25

**US3392120**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'I'	System	14 Oct 2020 17:16:25

**US3392120**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:39:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:16:37

**US3392120**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:39:55
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:16:37

US3392120

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:39:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:16:37

**US3392120**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:39:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:16:37

US3392120

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:39:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:16:41

**US3392120**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'I'	System	14 Oct 2020 17:16:41

**US3392120**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:22:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:34:14

US3392120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:22:34
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:34:14

US3392120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:22:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:34:14

US3392120

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:22:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:34:14

US3392120

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:22:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:34:18

**US3392120**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'I'	System	21 Oct 2020 19:34:18

**US3392120**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	16 Nov 2020 20:12:32

**US3392120**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered '02 Nov 2020'	Heather Salisbury (b) (4)	16 Nov 2020 20:12:32

US3392120

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered 'Clinic (Clinic)'	Heather Salisbury (b) (4)	16 Nov 2020 20:12:32

**US3392120**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'VISIT3'	System	16 Nov 2020 20:12:32

US3392120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered 'No (N)'	Heather Salisbury (b) (4)	16 Nov 2020 20:12:42

US3392120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered empty.	Heather Salisbury (b) (4)	16 Nov 2020 20:12:42

US3392120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered empty.	Heather Salisbury (b) (4)	16 Nov 2020 20:12:42

**US3392120**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered empty.	System	16 Nov 2020 20:12:42

US3392120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered empty.	Heather Salisbury (b) (4)	16 Nov 2020 20:12:42

**US3392120**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered empty.	Heather Salisbury (b) (4)	16 Nov 2020 20:12:42

**US3392120**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered empty.	Heather Salisbury (b) (4)	16 Nov 2020 20:12:42

**US3392120**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered empty.	Heather Salisbury (b) (4)	16 Nov 2020 20:12:42

**US3392120**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered empty.	System	16 Nov 2020 20:12:42

US3392120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered empty.	Heather Salisbury (b) (4)	16 Nov 2020 20:12:42

US3392120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered empty.	System	16 Nov 2020 20:12:42

US3392120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered empty.	Heather Salisbury (b) (4)	16 Nov 2020 20:12:42

US3392120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered empty.	System	16 Nov 2020 20:12:42

US3392120

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered empty.	Heather Salisbury (b) (4)	16 Nov 2020 20:12:42

**US3392120**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered empty.	System	16 Nov 2020 20:12:42

**US3392120**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48

**US3392120**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48

US3392120

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered 'No (N)'	Heather Salisbury (b) (4)	16 Nov 2020 20:12:46

US3392120

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered empty.	Heather Salisbury (b) (4)	16 Nov 2020 20:12:46

US3392120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	16 Nov 2020 20:13:11

US3392120

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered '02 Nov 2020'	Heather Salisbury (b) (4)	16 Nov 2020 20:13:11

**US3392120**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:25:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered '12:31'	Heather Salisbury (b) (4)	16 Nov 2020 20:13:11

**US3392120**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:25:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered '02 Nov 2020 12:31'	System	16 Nov 2020 20:13:11

US3392120

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:02
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	16 Nov 2020 20:13:15

**US3392120**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'I'	System	16 Nov 2020 20:13:15

US3392120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 64'	System	31 Aug 2020 15:22:55

US3392120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

[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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-31T00:01:45', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ce285040-0fda-4a31-8bd2-744622bc94c8'	System	31 Oct 2020 05:03:29
User entered 'Yes (Y)'	System	31 Oct 2020 05:03:29

US3392120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

Have you been exposed to someone with 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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-31T00:02:18', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ce285040-0fda-4a31-8bd2-744622bc94c8'	System	31 Oct 2020 05:03:29
User entered 'No (N)'	System	31 Oct 2020 05:03:29

US3392120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-31T00:02:40', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ce285040-0fda-4a31-8bd2-744622bc94c8'	System	31 Oct 2020 05:03:29
User entered 'No (N)'	System	31 Oct 2020 05:03:29

US3392120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-31T00:02:50', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ce285040-0fda-4a31-8bd2-744622bc94c8'	System	31 Oct 2020 05:03:29
User entered 'Yes (Y)'	System	31 Oct 2020 05:03:29

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-31T00:03:01', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ce285040-0fda-4a31-8bd2-744622bc94c8'	System	31 Oct 2020 05:03:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Oct 2020 05:03:29

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-10-31T00:03:20', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'ce285040-0fda-4a31-8bd2-744622bc94c8' User entered '31 Oct 2020 00:03:20'	System	31 Oct 2020 05:03:29
	System	31 Oct 2020 05:03:29

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 15:22:55

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 15:22:55

US3392120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 71'	System	31 Aug 2020 15:22:55

US3392120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

[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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-11-07T00:01:29', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '9194e382-e58f-49eb-ae19-7491c73bed42'	System	07 Nov 2020 06:03:13
User entered 'No (N)'	System	07 Nov 2020 06:03:13

US3392120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

Have you been exposed to someone with 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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-11-07T00:01:42', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '9194e382-e58f-49eb-ae19-7491c73bed42'	System	07 Nov 2020 06:03:13
User entered 'No (N)'	System	07 Nov 2020 06:03:13

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-11-07T00:01:47', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '9194e382-e58f-49eb-ae19-7491c73bed42' User entered '07 Nov 2020 00:01:47'	System	07 Nov 2020 06:03:13
	System	07 Nov 2020 06:03:13

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 15:22:55

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 15:22:55

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered 'Day 78'	System	31 Aug 2020 15:22:55

US3392120

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-11-14T00:04:16', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'c57f1433-7159-4199-a621-14c429bcc73d'	System	14 Nov 2020 06:04:35
User entered 'No (N)'	System	14 Nov 2020 06:04:35

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Have you been exposed to someone with 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 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-11-14T00:04:19', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'c57f1433-7159-4199-a621-14c429bcc73d'	System	14 Nov 2020 06:04:35
User entered 'No (N)'	System	14 Nov 2020 06:04:35

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-11-14T00:04:32', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'c57f1433-7159-4199-a621-14c429bcc73d' User entered '14 Nov 2020 00:04:32'	System	14 Nov 2020 06:04:35
	System	14 Nov 2020 06:04:35

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 15:22:55

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:34:07
Data entry locked.	System	31 Aug 2020 15:22:55
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 15:22:55

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-11-25T00:08:47', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4166a882-64b5-46f2-b8b5-40213786dfa8' User entered 'No (N)'	System	25 Nov 2020 06:09:12
	System	25 Nov 2020 06:09:12

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Have you been exposed to someone with 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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-11-25T00:08:56', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4166a882-64b5-46f2-b8b5-40213786dfa8' User entered 'No (N)'	System	25 Nov 2020 06:09:12

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-11-25T00:09:08', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '4166a882-64b5-46f2-b8b5-40213786dfa8' User entered '25 Nov 2020 00:09:08'	System	25 Nov 2020 06:09:12
	System	25 Nov 2020 06:09:12

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-02T00:01:37', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '60bce435-598d-49f8-a91f-97c1406f3b73'	System	02 Dec 2020 06:01:50
User entered 'No (N)'	System	02 Dec 2020 06:01:50

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Have you been exposed to someone with 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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-02T00:01:43', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '60bce435-598d-49f8-a91f-97c1406f3b73'	System	02 Dec 2020 06:01:50
User entered 'No (N)'	System	02 Dec 2020 06:01:50

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-02T00:01:48', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '60bce435-598d-49f8-a91f-97c1406f3b73' User entered '02 Dec 2020 00:01:48'	System	02 Dec 2020 06:01:50
	System	02 Dec 2020 06:01:50

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-09T02:36:25', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '3809f6c0-1928-4d54-a963-d319b19e276d' User entered 'No (N)'	System	09 Dec 2020 08:36:37
	System	09 Dec 2020 08:36:37

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Have you been exposed to someone with 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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-09T02:36:32', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '3809f6c0-1928-4d54-a963-d319b19e276d' User entered 'No (N)'	System	09 Dec 2020 08:36:37
	System	09 Dec 2020 08:36:37

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-09T02:36:35', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '3809f6c0-1928-4d54-a963-d319b19e276d' User entered '09 Dec 2020 02:36:35'	System	09 Dec 2020 08:36:37
	System	09 Dec 2020 08:36:37

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-17T21:40:18', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'c843e9f0-af6f-499c-b794-c0052c88a57c' User entered 'No (N)'	System	18 Dec 2020 03:40:37
	System	18 Dec 2020 03:40:37

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Have you been exposed to someone with 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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-17T21:40:24', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'c843e9f0-af6f-499c-b794-c0052c88a57c' User entered 'No (N)'	System	18 Dec 2020 03:40:37
	System	18 Dec 2020 03:40:37

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-17T21:40:34', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'c843e9f0-af6f-499c-b794-c0052c88a57c' User entered '17 Dec 2020 21:40:34'	System	18 Dec 2020 03:40:37
	System	18 Dec 2020 03:40:37

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-25T14:31:19', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '504f2309-de3e-4af6-9fdc-9cd02c9bfce7'	System	25 Dec 2020 20:31:28
User entered 'No (N)'	System	25 Dec 2020 20:31:28

US3392120

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:38

Have you been exposed to someone with 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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-25T14:31:22', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '504f2309-de3e-4af6-9fdc-9cd02c9bfce7'	System	25 Dec 2020 20:31:28
User entered 'No (N)'	System	25 Dec 2020 20:31:28

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-25T14:31:24', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '504f2309-de3e-4af6-9fdc-9cd02c9bfce7' User entered '25 Dec 2020 14:31:24'	System	25 Dec 2020 20:31:28
	System	25 Dec 2020 20:31:28

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-30T00:01:42', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5e099661-b62f-4771-9fd4-dbf5befda334'	System	30 Dec 2020 06:01:55
User entered 'No (N)'	System	30 Dec 2020 06:01:55

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Have you been exposed to someone with 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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-30T00:01:47', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5e099661-b62f-4771-9fd4-dbf5befda334'	System	30 Dec 2020 06:01:55
User entered 'No (N)'	System	30 Dec 2020 06:01:55

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2020-12-30T00:01:50', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5e099661-b62f-4771-9fd4-dbf5befda334' User entered '30 Dec 2020 00:01:50'	System	30 Dec 2020 06:01:55
	System	30 Dec 2020 06:01:55

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2021-01-06T00:32:08', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8f34acee-5f82-4d03-9ff9-18b7680eaa48' User entered 'No (N)'	System	06 Jan 2021 06:32:17
	System	06 Jan 2021 06:32:17

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Have you been exposed to someone with 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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2021-01-06T00:32:11', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8f34acee-5f82-4d03-9ff9-18b7680eaa48'	System	06 Jan 2021 06:32:17
User entered 'No (N)'	System	06 Jan 2021 06:32:17

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2021-01-06T00:32:14', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8f34acee-5f82-4d03-9ff9-18b7680eaa48' User entered '06 Jan 2021 00:32:14'	System	06 Jan 2021 06:32:17
	System	06 Jan 2021 06:32:17

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2021-01-15T11:24:58', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5164303f-1222-48fc-81c6-fd97638ce6a9' User entered 'No (N)'	System	15 Jan 2021 17:26:17
	System	15 Jan 2021 17:26:17

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Have you been exposed to someone with 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 (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2021-01-15T11:25:02', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5164303f-1222-48fc-81c6-fd97638ce6a9' User entered 'No (N)'	System	15 Jan 2021 17:26:17
	System	15 Jan 2021 17:26:17

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (781DC3CB-AEB5-4E29-94C7-A4440B2A3BC0)', Time: '2021-01-15T11:26:13', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '5164303f-1222-48fc-81c6-fd97638ce6a9' User entered '15 Jan 2021 11:26:13'	System	15 Jan 2021 17:26:17
	System	15 Jan 2021 17:26:17

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[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 (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-03-17T11:35:33-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'e3a378d7-cb9c-40b4-8f90-10e0daafd294'	System	17 Mar 2021 16:35:48
User entered 'No (N)'	System	17 Mar 2021 16:35:48

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Have you been exposed to someone with 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 (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-03-17T11:35:41-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'e3a378d7-cb9c-40b4-8f90-10e0daafd294'	System	17 Mar 2021 16:35:48
User entered 'No (N)'	System	17 Mar 2021 16:35:48

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-03-17T11:35:45-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'e3a378d7-cb9c-40b4-8f90-10e0daafd294' User entered '17 Mar 2021 11:35:45'	System	17 Mar 2021 16:35:48
	System	17 Mar 2021 16:35:48

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[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 (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-03-24T12:28:52-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '340ae603-47fa-4501-a25e-9637b579ca89'	System	24 Mar 2021 17:29:09
User entered 'No (N)'	System	24 Mar 2021 17:29:09

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Have you been exposed to someone with 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 (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-03-24T12:28:59-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '340ae603-47fa-4501-a25e-9637b579ca89'	System	24 Mar 2021 17:29:09
User entered 'No (N)'	System	24 Mar 2021 17:29:09

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-03-24T12:29:03-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '340ae603-47fa-4501-a25e-9637b579ca89' User entered '24 Mar 2021 12:29:03'	System	24 Mar 2021 17:29:09
	System	24 Mar 2021 17:29:09

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[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 (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-03-31T09:43:25-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'fb053eab-1028-440a-80fb-ce4472b3c60b'	System	31 Mar 2021 14:43:35
User entered 'No (N)'	System	31 Mar 2021 14:43:35

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Have you been exposed to someone with 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 (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-03-31T09:43:30-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'fb053eab-1028-440a-80fb-ce4472b3c60b'	System	31 Mar 2021 14:43:35
User entered 'No (N)'	System	31 Mar 2021 14:43:35

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-03-31T09:43:33-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'fb053eab-1028-440a-80fb-ce4472b3c60b' User entered '31 Mar 2021 09:43:33'	System	31 Mar 2021 14:43:35
	System	31 Mar 2021 14:43:35

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[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 (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-04-07T00:14:14-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '88d720a9-436f-4a6a-9c23-6c54d6894a9d' User entered 'No (N)'	System	07 Apr 2021 05:14:25
	System	07 Apr 2021 05:14:25

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Have you been exposed to someone with 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 (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-04-07T00:14:19-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '88d720a9-436f-4a6a-9c23-6c54d6894a9d'	System	07 Apr 2021 05:14:25
User entered 'No (N)'	System	07 Apr 2021 05:14:25

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-04-07T00:14:22-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '88d720a9-436f-4a6a-9c23-6c54d6894a9d' User entered '07 Apr 2021 00:14:22'	System	07 Apr 2021 05:14:25
	System	07 Apr 2021 05:14:25

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[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 (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-04-14T00:17:14-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8b288388-da21-4323-b0c6-214227d7a37c'	System	14 Apr 2021 05:17:31
User entered 'No (N)'	System	14 Apr 2021 05:17:31

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Have you been exposed to someone with 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 (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-04-14T00:17:24-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8b288388-da21-4323-b0c6-214227d7a37c'	System	14 Apr 2021 05:17:31
User entered 'No (N)'	System	14 Apr 2021 05:17:31

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-04-14T00:17:27-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '8b288388-da21-4323-b0c6-214227d7a37c'	System	14 Apr 2021 05:17:31
User entered '14 Apr 2021 00:17:27'	System	14 Apr 2021 05:17:31

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[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 (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-04-22T19:24:41-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '71ad2339-111d-41f0-8519-0146832e73f4' User entered 'No (N)'	System	23 Apr 2021 00:24:49
	System	23 Apr 2021 00:24:49

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Have you been exposed to someone with 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 (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-04-22T19:24:44-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '71ad2339-111d-41f0-8519-0146832e73f4' User entered 'No (N)'	System	23 Apr 2021 00:24:49
	System	23 Apr 2021 00:24:49

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-04-22T19:24:47-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '71ad2339-111d-41f0-8519-0146832e73f4'	System	23 Apr 2021 00:24:49
User entered '22 Apr 2021 19:24:47'	System	23 Apr 2021 00:24:49

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

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 (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-04-28T00:02:18-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'be7a4962-81b0-4ffc-8740-fb8feca8aa7f'	System	29 Apr 2021 05:58:07
User entered 'No (N)'	System	29 Apr 2021 05:58:07

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

Have you been exposed to someone with 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 (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-04-28T00:02:23-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'be7a4962-81b0-4ffc-8740-fb8feca8aa7f'	System	29 Apr 2021 05:58:07
User entered 'No (N)'	System	29 Apr 2021 05:58:07

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-04-28T00:02:26-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: 'be7a4962-81b0-4ffc-8740-fb8feca8aa7f'	System	29 Apr 2021 05:58:07
User entered '28 Apr 2021 00:02:26'	System	29 Apr 2021 05:58:07

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 20:48:47

**US3392120**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:48:47
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 20:48:47

US3392120

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:25:38

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 07:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-03-16T12:05:38-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '77c373d8-8f66-418a-b056-518b3ef88b2f' User entered 'No (N)'	System	16 Mar 2021 17:06:50
	System	16 Mar 2021 17:06:50

**US3392120**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C856ADBA-7D63-470D-AA32-D54A59FDBE26)', Time: '2021-03-16T12:05:42-05:00', User OID: 'PatientReportedOutcome (US3392120)', ODM File OID: '77c373d8-8f66-418a-b056-518b3ef88b2f' User entered '16 Mar 2021 12:05:42'	System	16 Mar 2021 17:06:50
	System	16 Mar 2021 17:06:50

**US3392120**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:56:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 19:56:43

**US3392120**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:56:03
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 19:56:43

US3392120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:56:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:56:43

US3392120

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:56:03
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:56:43

US3392120

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:56:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 19:56:49

**US3392120**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 11:18:48
User entered 'I'	System	23 Nov 2020 19:56:49

**US3392120**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:15
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 21:25:24

**US3392120**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:15
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '15 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 21:25:24

**US3392120**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:15
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:25:24

**US3392120**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:15
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 21:25:24

US3392120

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:15
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 21:25:06

**US3392120**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:15
User entered 'I'	System	15 Dec 2020 21:25:06

**US3392120**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:47
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:46:57

US3392120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:47
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:46:57

**US3392120**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:47
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:46:57

US3392120

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:47
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:46:57

**US3392120**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:47
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:47:03

**US3392120**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:47
User entered 'I'	System	04 Feb 2021 23:47:03

**US3392120**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:40:39
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:57:38

**US3392120**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:40:39
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:57:38

**US3392120**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:40:39
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:57:38

**US3392120**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:40:39
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:57:38

**US3392120**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:40:39
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:57:42

**US3392120**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:40:39
User entered 'I'	System	24 Feb 2021 23:57:42

**US3392120**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 20:12:46

**US3392120**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 20:12:46

US3392120

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 20:12:46

**US3392120**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User entered 'VISIT4'	System	16 Mar 2021 20:12:46

US3392120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'No (N)'	(b) (4)	01 Apr 2021 16:13:01

US3392120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4)	01 Apr 2021 16:13:01

**US3392120**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4)	01 Apr 2021 16:13:01

**US3392120**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User entered empty.	System	01 Apr 2021 16:13:01

US3392120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4)	01 Apr 2021 16:13:01

US3392120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4)	01 Apr 2021 16:13:01

**US3392120**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4)	01 Apr 2021 16:13:01

US3392120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4)	01 Apr 2021 16:13:01

**US3392120**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User entered empty.	System	01 Apr 2021 16:13:01

US3392120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4)	01 Apr 2021 16:13:01

US3392120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User entered empty.	System	01 Apr 2021 16:13:01

US3392120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4)	01 Apr 2021 16:13:01

**US3392120**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User entered empty.	System	01 Apr 2021 16:13:01

US3392120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4)	01 Apr 2021 16:13:01
	Brandon Illickal (b) (4)	

US3392120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User entered empty.	System	01 Apr 2021 16:13:01

US3392120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14

US3392120

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14

US3392120

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 20:12:50

US3392120

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 20:12:50

US3392120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 20:13:01

US3392120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 20:13:01

US3392120

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '11:15'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 20:13:01

**US3392120**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:25:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User entered '16 Mar 2021 11:15'	System	16 Mar 2021 20:13:01

US3392120

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 20:13:05

**US3392120**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:14
User entered 'I'	System	16 Mar 2021 20:13:05

**US3392120**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 16:25:16

**US3392120**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 16:25:16

**US3392120**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 16:25:16

**US3392120**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 16:25:16

US3392120

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 16:25:19

**US3392120**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Apr 2021 16:25:19

**US3392120**

**Folder: Covid-19 Assessment 22 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:25:38**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '22 Sep 2020'	Heather Salisbury (b) (4)	08 Dec 2020 21:46:58

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:25:38

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '16:00'	Heather Salisbury (b) (4)	08 Dec 2020 21:46:58

**US3392120**

**Folder: Covid-19 Assessment 22 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:25:38**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '22 Sep 2020 16:00'	System	08 Dec 2020 21:46:58

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:25:38

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Heather Salisbury (b) (4)	08 Dec 2020 21:46:58

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:25:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:26:50
User entered 'No (N)' reason for change: Data Entry Error	Heather Salisbury (b) (4)	08 Dec 2020 21:47:34
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	08 Dec 2020 21:46:58

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4)	25 Jan 2021 22:04:14



US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '0'	(b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '99' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:43:48
User entered empty.	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	25 Jan 2021 23:43:48
User entered empty.	System	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '98.0' F reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Brandon Illickal (b) (4)	25 Jan 2021 23:43:48
User entered empty.	(b) (4)	
	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:43:48
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 22:04:14

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Day 2 (Day 2)'	(b) (4)	25 Jan 2021 23:45:07
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '23 Sep 2020'	(b) (4)	25 Jan 2021 23:45:07

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '0'	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:45:07

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered missing code ND - Not Done.	(b) (4)	25 Jan 2021 23:45:07

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	25 Jan 2021 23:45:07

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered missing code ND - Not Done.	(b) (4)	25 Jan 2021 23:45:07

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:45:07
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Mild (Mild)'	(b) (4)	25 Jan 2021 23:45:07
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Mild (Mild)'	(b) (4)	25 Jan 2021 23:45:07
	Brandon Illickal (b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:45:07
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:45:07
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:45:07
	Brandon Illickal (b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:45:07
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:45:07
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:45:07

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:45:07

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:45:07
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:45:07

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:45:07

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:45:07
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:45:07
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:45:07
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Day 3 (Day 3)'	(b) (4)	25 Jan 2021 23:45:36
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '24 Sep 2020'	(b) (4)	25 Jan 2021 23:45:36
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User closed query 'Please complete eCRF as per CCG: "If a symptom is not assessed on a specific Day, enter 'ND' for the symptom. Do not leave the field blank. If a symptom is reported but the severity has not been provided, select 'Mild' for the symptom from the dropdown list.'" (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:59:14
Query 'Please complete eCRF as per CCG: "If a symptom is not assessed on a specific Day, enter 'ND' for the symptom. Do not leave the field blank. If a symptom is reported but the severity has not been provided, select 'Mild' for the symptom from the dropdown list.'" answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 21:22:32
User opened query 'Please complete eCRF as per CCG: "If a symptom is not assessed on a specific Day, enter 'ND' for the symptom. Do not leave the field blank. If a symptom is reported but the severity has not been provided, select 'Mild' for the symptom from the dropdown list.'" (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 14:35:16
Query 'Please complete eCRF' canceled (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 14:34:39
User opened query 'Please complete eCRF' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 14:34:33
User entered 'I'	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4)	25 Jan 2021 23:45:36
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered empty.	System	25 Jan 2021 23:45:36

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4)	25 Jan 2021 23:45:36
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:22:25
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:45:36

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Day 4 (Day 4)'	(b) (4)	25 Jan 2021 23:46:19

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '25 Sep 2020'	(b) (4)	25 Jan 2021 23:46:19

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '0'	(b) (4)	25 Jan 2021 23:46:19

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered missing code ND - Not Done.	(b) (4)	25 Jan 2021 23:46:19

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '%'	System	25 Jan 2021 23:46:19

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered missing code ND - Not Done.	(b) (4)	25 Jan 2021 23:46:19

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:46:19
	Brandon Illickal (b) (4)	

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:38

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:27:33

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:38

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:27:33

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:38

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:27:33

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:38

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:27:33

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:38

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:27:33

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:38

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:27:33

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:38

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:27:33

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:38

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:27:33

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:38

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:27:33

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:38

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User entered '0'	System	04 Jan 2021 22:27:33

US3392120

Folder: Covid-19 Assessment 22 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:25:38

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:50:58
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	08 Dec 2020 21:47:06

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:25:38**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:25:38**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:25:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:25:38**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:25:38**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:25:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:25:38**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:25:38**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:25:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:25:38**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:25:38**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:25:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:07:02

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:02:12

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:02:12

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[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 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:02:12

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User entered 'SICKD1'	System	31 Oct 2020 18:02:12

US3392120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:03:19

US3392120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:03:19

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '16:10'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:03:19

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User entered '22 Sep 2020 16:10'	System	31 Oct 2020 18:03:19

US3392120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:03:19
DataPoint set to visible.	System	31 Oct 2020 18:02:12

US3392120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:03:19
DataPoint set to visible.	System	31 Oct 2020 18:02:12

US3392120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:03:19

US3392120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:03:19

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:03:19

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '68'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:03:19

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User entered 'bpm'	System	31 Oct 2020 18:03:19

US3392120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '16'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:03:19

US3392120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User entered 'breaths/min'	System	31 Oct 2020 18:03:19

US3392120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '108'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:03:19

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User entered 'mmHg'	System	31 Oct 2020 18:03:19

US3392120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '74'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:03:19

US3392120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User entered 'mmHg'	System	31 Oct 2020 18:03:19

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24

US3392120

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24

US3392120

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:03:59

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:25:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:03:59

US3392120

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:25:38

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:04:37

US3392120

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:25:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:24
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please confirm date of SARS-CoV-2 serum sample collection as date is discrepant with date of illness visit.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 11:10:42
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please confirm date of SARS-CoV-2 serum sample collection as date is discrepant with date of illness visit.' answered with 'DATA CORRECTED' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 18:41:35
User entered '22 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 18:41:25
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please confirm date of SARS-CoV-2 serum sample collection as date is discrepant with date of illness visit.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 02:50:25
User entered '30 Sep 2020'	(b) (4), (b) (6)	31 Oct 2020 18:04:37

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	31 Oct 2020 18:02:12

**US3392120**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:38**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	31 Oct 2020 18:02:12

US3392120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:13:31

US3392120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:13:31

**US3392120**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:13:31

**US3392120**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 21:13:31

US3392120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:38

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:13:45

US3392120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:38

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '0'	(b) (4) Brandon Illickal (b) (4)	16 Mar 2021 17:02:44
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:33:38

**US3392120**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:25:38**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:13:45

US3392120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Brandon Illickal (b) (4)	16 Mar 2021 17:02:44
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:33:38

US3392120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:13:45

US3392120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:13:45

**US3392120**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:25:38**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 03:45:48
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	15 Jan 2021 21:13:45

US3392120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 03:45:48
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	15 Jan 2021 21:13:45

US3392120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:13:45

**US3392120**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:25:38**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User entered empty.	System	15 Jan 2021 21:13:45

**US3392120**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:25:38**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User entered empty.	System	15 Jan 2021 21:13:45

US3392120

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:14:03

**US3392120**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:25:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:14:03

**US3392120**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:25:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '10:53'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:14:03

**US3392120**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:25:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User entered '15 Jan 2021 10:53'	System	15 Jan 2021 21:14:03

**US3392120**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:25:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:14:13

**US3392120**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:25:38**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:14:13

**US3392120**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:25:38**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:07
User entered '10:55'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:14:13

**US3392120**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:25:38**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:06:54
User entered '15 Jan 2021 10:55'	System	15 Jan 2021 21:14:13

US3392120

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:25:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:25:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:27:59
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	02 Nov 2020 22:51:46

US3392120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:38

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:29:06
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:53:33
User entered	System	03 Nov 2020 19:53:26
'USA-US119-2020-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	03 Nov 2020 19:53:26

US3392120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:27:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:27:11
Data point term sent to Coder	System	02 Nov 2020 22:57:39
User entered 'myocardial infarction'	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

US3392120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered 'Yes (Y)'	Brandon Illickal (b) (4)  	02 Nov 2020 22:57:19

US3392120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered 'No (N)'	Brandon Illickal (b) (4)  	02 Nov 2020 22:57:19

US3392120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered 'No (N)'	Brandon Illickal (b) (4)  	02 Nov 2020 22:57:19

US3392120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered '24 Oct 2020'	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered empty.	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 22:57:19

US3392120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered 'No (N)'	Brandon Illickal (b) (4)  	02 Nov 2020 22:57:19

US3392120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered '26 Oct 2020'	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:38**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered empty.	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 22:57:19

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered 'Grade 3/Severe (Grade 3/Severe)'	Brandon Illickal (b) (4)  	02 Nov 2020 22:57:19

US3392120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered 'Yes (Y)'	Brandon Illickal (b) (4)  	02 Nov 2020 22:57:19

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered '0'	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

US3392120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered '0'	Brandon Illickal (b) (4)  	02 Nov 2020 22:57:19

US3392120

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered 'I'	Brandon Illickal (b) (4)  	02 Nov 2020 22:57:19

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered '24 Oct 2020'	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered '26 Oct 2020'	Brandon Illickal (b) (4)  	02 Nov 2020 22:57:19

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered 'No (N)'	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered empty.	Brandon Illickal (b) (4)  	02 Nov 2020 22:57:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered '0'	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered '0'	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered '0'	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)  	02 Nov 2020 22:57:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)  	02 Nov 2020 22:57:19

US3392120

Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
User closed query 'PV Query: As the last dose of study drug was given on 30 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 15:07:00
Query 'PV Query: As the last dose of study drug was given on 30 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Brandon Illickal (b) (4)	25 Nov 2020 17:50:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:37:32
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:37:32
User opened query 'PV Query: As the last dose of study drug was given on 30 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 22:33:49
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:29:06
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 22:57:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 22:57:33
User entered 'None (NONE)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	02 Nov 2020 22:57:33
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 22:57:19
User entered empty.	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:38**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered '0'	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered 'I'	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered 'I'	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brandon Illickal (b) (4)  	02 Nov 2020 22:57:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered empty.	Brandon Illickal (b) (4)  	02 Nov 2020 22:57:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:55:48
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 received. ' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 19:55:45
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received. ' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 19:55:43
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'documents have been submitted' (Site from Safety).	Brandon Illickal (b) (4)	16 Mar 2021 21:14:43
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 received. ' answered with 'Result has been sent to Safety_Moderna@iqvia.com' (Site from Safety).	Brandon Illickal (b) (4)	16 Mar 2021 21:07:57
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received. ' answered with 'documents have been sent to Safety_Moderna@iqvia.com' (Site from Safety).	Brandon Illickal (b) (4)	16 Mar 2021 21:07:43

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PRESENTED TO ER WITH CHEST PAIN , DX'D WITH AMI FOR WHICH HE UNDERWENT EMERGENT PTCA X 2  (RCA LESIONS); ADMITTED X 2 NIGHTS. NO ICU. NOW ASYMPTOMATIC. SUBJECT HAS A MEDICAL HISTORY OF MYOCARDIAL INFARCTION.' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	16 Mar 2021 21:05:08
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 16:37:47
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 received. ' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 16:37:33
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received. ' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 16:37:17
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 20:39:42
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 20:39:39
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 20:39:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'SITE IS STILL WAITING TO RECEIVE MEDICAL RECORDS.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 15:43:47
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 IS STILL WAITING TO RECEIVE MEDICAL RECORDS.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 15:43:40
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'SITE IS STILL WAITING TO RECEIVE MEDICAL RECORDS.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 15:43:34
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 16:58:16
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)	03 Dec 2020 16:58:04
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)	03 Dec 2020 16:58:01
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 15:07:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
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)	30 Nov 2020 15:07:11
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)	30 Nov 2020 15:07:08
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 15:07:04
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'narrative updated' (Site from Safety). DataPoint Un-verified.	Brandon Illickal (b) (4)	25 Nov 2020 17:54:11
	Brandon Illickal (b) (4)	25 Nov 2020 17:53:59
User entered 'PRESENTED TO ER WITH CHEST PAIN , DX'D WITH AMI FOR WHICH HE UNDERWENT EMERGENT PTCA X 2 ( RCA LESIONS ); ADMITTED X 2 NIGHTS. NO ICU. NOW ASYMPTOMATIC. Subject has a medical history of myocardial infarction, hypercholesterolemia, coronary artery disease, and hypertension since 2009.' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	25 Nov 2020 17:53:59
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'hospital records have been requested. Data will be entered when records are received.' (Site from Safety).	Brandon Illickal (b) (4)	25 Nov 2020 17:52:23
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 'hospital records have been requested. Data will be entered when records are received.' (Site from Safety).	Brandon Illickal (b) (4)	25 Nov 2020 17:52:16

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EAB) (1725)

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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.' 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 17:52:08
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 22:34:53
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)	12 Nov 2020 22:34:22
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)	12 Nov 2020 22:34:09
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 22:33:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:29:06
User entered 'Presented to ER with chest pain , dx'd with AMI for which he underwent emergent PTCA x 2 ( RCA lesions ); Admitted x 2 nights. No ICU. Now asymptomatic.'	Brandon Illickal (b) (4)	02 Nov 2020 22:57:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 22:57:19

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Nov 2020 22:57:19

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Nov 2020 22:57:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Mar 2021 22:21:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 22:21:06
Data point term sent to Coder	System	16 Mar 2021 22:20:13
User entered 'type ii diabetes'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '24 Oct 2020'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:25:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 22:19:51

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	16 Mar 2021 22:20:05
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	16 Mar 2021 22:20:05
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Mar 2021 22:19:51
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:25:38**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:25:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 22:19:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
User entered 'Not Related (NOT RELATED)'	(b) (4) Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'None (NONE)'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:25:38**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '1'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Mar 2021 22:20:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:19:51

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Mar 2021 22:19:51

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 22:19:51

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Leg spasm - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Mar 2021 12:08:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:08:48
Data point term sent to Coder	System	16 Mar 2021 22:22:15
User entered 'muscle spasms, right leg'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42
	(b) (4)	
	(b) (4)	

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	16 Mar 2021 22:22:07
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	16 Mar 2021 22:22:07
User entered '10 Mar 2021' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Mar 2021 22:22:07
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	16 Mar 2021 22:21:42
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	16 Mar 2021 22:21:42
User entered '10 Mar 2020'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 22:21:42

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'None (NONE)'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered 'I'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

US3392120

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:06
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:21:42

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Mar 2021 22:21:42

**US3392120**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 22:21:42

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:25:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:25:17
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:13:02

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Feb 2021 00:34:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 00:34:04
Data point term sent to Coder	System	25 Feb 2021 00:32:58
Coding entries removed.	Brandon Illickal (b) (4)	25 Feb 2021 00:32:32
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:32:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:32:45
Data point term sent to Coder	System	21 Oct 2020 20:15:03
User entered 'FINASTERIDE'	(b) (4), (b) (6)	21 Oct 2020 20:14:36

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:14:36

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 14:10:31
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:10:25
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'MH updated' (Site from DM).	Brandon Illickal (b) (4)	25 Feb 2021 00:43:51
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate' answered with 'indication updated' (Site from DM).	Brandon Illickal (b) (4)	25 Feb 2021 00:43:35
User entered 'Urinary retention' reason for change: Data Entry Error	Brandon Illickal (b) (4)	25 Feb 2021 00:32:32
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 08:13:24
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 08:13:00
User entered 'TACHYCARDIA'	(b) (4), (b) (6)	21 Oct 2020 20:14:36

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '5'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:14:36

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:14:36

US3392120

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:25:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:14:36

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:14:36

US3392120

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:25:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:14:36

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:14:36

US3392120

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:25:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:14:36

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'UN Oct 2014'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:14:36

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:14:36

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:14:36

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:14:36

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:14:36

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:14:36

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:14:36

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 20:14:36

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Mar 2021 22:09:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 22:09:57
Data point term sent to Coder Coding entries removed.	System Brandon Illickal (b) (4)	16 Mar 2021 22:08:39 16 Mar 2021 22:08:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 04:59:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 04:59:28
Data point term sent to Coder User entered 'SPIRONOLATONE'	System (b) (4), (b) (6)	21 Oct 2020 20:16:04 21 Oct 2020 20:15:59

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:15:59

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 06:00:03
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:59:49
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	16 Mar 2021 22:08:43
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	16 Mar 2021 22:08:38
User entered 'hypertension' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Mar 2021 22:08:31
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 08:16:55
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 08:16:48
User entered 'TACHYCARDIA'	(b) (4), (b) (6)	21 Oct 2020 20:15:59

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '100'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:15:59

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:15:59

US3392120

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:25:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:15:59

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'twice daily (BID)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:26:30
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Oct 2020 20:15:59

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:15:59

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:15:59

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:25:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:15:59

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'UN Oct 2014'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:15:59

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:15:59

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:15:59

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:15:59

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:15:59

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Oct 2020 20:26:30
User entered '1'	System	21 Oct 2020 20:15:59

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:15:59

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 20:15:59

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 13:07:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 13:07:42
Data point term sent to Coder Coding entries removed.	System Brandon Illickal (b) (4)	16 Mar 2021 22:10:49 16 Mar 2021 22:10:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:18:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:18:29
Data point term sent to Coder Data point term sent to Coder User entered 'METOPROLOL TARTATE'	System System (b) (4), (b) (6)	21 Oct 2020 20:25:21 21 Oct 2020 20:18:08 21 Oct 2020 20:17:16

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:17:16

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 05:59:12
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'data corrected' (Site from DM).	Brandon Illickal (b) (4)	16 Mar 2021 22:10:17
User entered 'coronary artery disease' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Mar 2021 22:10:11
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 08:16:32
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 20:25:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 20:25:21
User entered 'BETA BLOCKER HEART DISEASE' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:25:21
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 20:17:16
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:17:16

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '25'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:17:16

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:17:16

US3392120

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:17:16

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'twice daily (BID)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:26:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Oct 2020 20:17:16

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:17:16

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:17:16

US3392120

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:17:16

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'UN Mar 2009'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:17:16

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:17:16

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:17:16

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:17:16

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:17:16

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Oct 2020 20:26:53
User entered '1'	System	21 Oct 2020 20:17:16

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:17:16

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 20:17:16

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 20:27:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:27:43
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	21 Oct 2020 20:26:22 21 Oct 2020 20:25:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: ATORVASTATINE [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:23:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:23:41
Data point term sent to Coder User entered 'ATORVASTATINE'	System (b) (4), (b) (6)	21 Oct 2020 20:19:09 21 Oct 2020 20:18:39

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 20:25:59
User entered 'HYPERCHOLESTEROLEMIA' reason for change: Data Entry Error	System	21 Oct 2020 20:25:59
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 20:18:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:18:39

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:25:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '80'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39

US3392120

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:25:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:25:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39

US3392120

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:25:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:25:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'UN Mar 2009'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:25:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:25:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:18:39

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:25:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:18:39

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:18:39

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 20:18:39

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Oct 2020 20:21:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 20:21:38
Data point term sent to Coder	System	21 Oct 2020 20:21:13
User entered 'ESCITALOPRAM'	(b) (4), (b) (6)	21 Oct 2020 20:20:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:20:34

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'ANXIETY'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:20:34

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '10'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:20:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:20:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:20:34

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:20:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:20:34

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:20:34

US3392120

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:20:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'UN Apr 2009'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:20:34

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:20:34

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:20:34

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:20:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:20:34

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:20:34

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:20:34

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 20:20:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL VALERATE, PRODUCTSYNONYM: DELESTROGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 08:15:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 08:15:39
Data point term sent to Coder	System	16 Mar 2021 22:06:19
Data point term sent to Coder	System	16 Mar 2021 22:05:17
Coding entries removed.	Brandon Illickal (b) (4)	16 Mar 2021 22:05:11
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL VALERATE, PRODUCTSYNONYM: DELESTROGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:18:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:18:46
Data point term sent to Coder	System	21 Oct 2020 20:22:17
User entered 'DELSTROGEN'	(b) (4), (b) (6)	21 Oct 2020 20:21:57

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:25:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:21:57

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 05:54:46
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'indication updated' (Site from DM).	Brandon Illickal (b) (4)	16 Mar 2021 22:05:20
User entered 'gender dysphoria' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Mar 2021 22:05:11
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 08:11:44
User entered 'HORMONE REPLACEMENT'	(b) (4), (b) (6)	21 Oct 2020 20:21:57

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 05:55:47
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'data corrected' (Site from DM).	Brandon Illickal (b) (4)	16 Mar 2021 22:05:53
User entered '0.25' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Mar 2021 22:05:46
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 08:11:58
User entered '100'	(b) (4), (b) (6)	21 Oct 2020 20:21:57

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:21:57

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:21:57

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 05:56:13
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'data corrected' (Site from DM).	Brandon Illickal (b) (4)	16 Mar 2021 22:06:00
User entered 'every week (QS)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Mar 2021 22:05:46
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 08:12:11
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Oct 2020 20:21:57

US3392120

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:25:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:21:57

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User closed query ' Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM). Query '	(b) (4) (b) (4), (b) (6)	17 Mar 2021 05:56:51
Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	16 Mar 2021 22:06:09
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	16 Mar 2021 22:06:04
User opened query ' Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 08:12:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Oct 2020 20:21:57

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:21:57

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:25:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'UN Oct 2014'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:21:57

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:25:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:21:57

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:25:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:21:57

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:21:57

US3392120

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:25:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:21:57

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:25:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:21:57

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:21:57

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	16 Mar 2021 22:05:46
User entered '804 (804)'	System	21 Oct 2020 20:21:57

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Nov 2020 19:33:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:33:21
Data point term sent to Coder	System	02 Nov 2020 22:59:40
User entered 'brilinta'	Brandon Illickal (b) (4) (b) (4) (b) (4)	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'myocardial infarction'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '90'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'mg (mg)'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'once daily (QD)'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'Oral (ORAL)'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '24 Oct 2020'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:11

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:25:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 22:59:11

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 22:59:11

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 22:59:11

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
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)	05 Nov 2020 19:36:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:36:09
Data point term sent to Coder	System	02 Nov 2020 23:00:40
User entered 'metformin'	Brandon Illickal (b) (4) (b) (4) (b) (4)	02 Nov 2020 22:59:52

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:52

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'AE form has been updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 05:58:22
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	Brandon Illickal (b) (4)	16 Mar 2021 22:18:33
User entered 'Type II Diabetes'	(b) (4), (b) (6)	16 Feb 2021 08:14:24
	Brandon Illickal (b) (4)	02 Nov 2020 22:59:52

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '500'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:52

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'mg (mg)'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:52

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	02 Nov 2020 22:59:52

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'twice daily (BID)'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:52

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	02 Nov 2020 22:59:52

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'Oral (ORAL)'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:52

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	02 Nov 2020 22:59:52

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '24 Oct 2020'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:52

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:38

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:52

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:25:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:52

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	02 Nov 2020 22:59:52

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	02 Nov 2020 22:59:52

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:25:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Nov 2020 22:59:52

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 22:59:52

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 22:59:52

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 08:22:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 08:22:02
Data point term sent to Coder	System	31 Mar 2021 17:56:28
User entered 'ASPIRIN' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 17:56:19
Data point term sent to Coder	System	31 Mar 2021 17:55:28
Coding entries removed.	(b) (4), (b) (6)	31 Mar 2021 17:55:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 07:27:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 07:27:39
Data point term sent to Coder	System	16 Mar 2021 22:24:16
User entered 'apirin'	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:45:44
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'this medication was given secondary to myocardial infarction; this AE is already listed' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 17:56:00
User entered 'WORSENING OF CARDIOVASCULAR DISEASE/secondary to myocardial infarction' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 17:55:04
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 16:12:12
User entered 'worsening of cardiovascular disease'	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '81'	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'mg (mg)'	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'once daily (QD)'	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'Oral (ORAL)'	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '29 Oct 2020'	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	16 Mar 2021 22:23:40

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:25:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 22:23:40

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 22:23:40

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Mar 2021 22:23:40

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Mar 2021 10:03:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 10:03:41
Data point term sent to Coder	System	16 Mar 2021 22:25:17
User entered 'gabapentin'	Brandon Illickal (b) (4) (b) (4) (b) (4)	16 Mar 2021 22:24:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	16 Mar 2021 22:24:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'muscle spasms, right leg'	(b) (4) Brandon Illickal (b) (4)	16 Mar 2021 22:24:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '100'	Brandon Illickal (b) (4)	16 Mar 2021 22:24:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'mg (mg)'	Brandon Illickal (b) (4)	16 Mar 2021 22:24:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:24:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'once daily (QD)'	Brandon Illickal (b) (4)	16 Mar 2021 22:24:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:24:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'Oral (ORAL)'	Brandon Illickal (b) (4)	16 Mar 2021 22:24:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:24:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '10 Mar 2021'	Brandon Illickal (b) (4)	16 Mar 2021 22:24:34

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:25:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:24:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	16 Mar 2021 22:24:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:24:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	16 Mar 2021 22:24:34

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:25:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 22:24:34

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 22:24:34

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Mar 2021 22:24:34

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Mar 2021 12:15:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:15:45
Data point term sent to Coder	System	16 Mar 2021 22:27:19
User entered 'methocarbamol'	Brandon Illickal (b) (4) (b) (4) (b) (4)	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'muscle spasms, right leg'	Brandon Illickal (b) (4)	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '500'	Brandon Illickal (b) (4)	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'mg (mg)'	Brandon Illickal (b) (4)	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'twice daily (BID)'	Brandon Illickal (b) (4)	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Oral (ORAL)'	(b) (4) Brandon Illickal (b) (4)	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '10 Mar 2021'	Brandon Illickal (b) (4)	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	16 Mar 2021 22:26:27

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:25:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Mar 2021 22:26:27

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 22:26:27

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Mar 2021 22:26:27

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 13:11:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 13:11:40
Data point term sent to Coder	System	31 Mar 2021 17:59:31
Coding entries removed.	(b) (4), (b) (6)	31 Mar 2021 17:58:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:56:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:56:43
Data point term sent to Coder	System	16 Mar 2021 22:28:19
User entered 'ticagrelor'	Brandon Illickal (b) (4)	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Mar 2021 17:58:49
User closed query 'Per CDM: Please confirm prophylaxis = "Yes" as there is a diagnosed condition for which this medication is taken for. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:23:50
Query 'Per CDM: Please confirm prophylaxis = "Yes" as there is a diagnosed condition for which this medication is taken for. Thank you' answered with 'Corrected' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 15:52:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 15:51:55
User opened query 'Per CDM: Please confirm prophylaxis = "Yes" as there is a diagnosed condition for which this medication is taken for. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 14:25:50
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:46:07
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'this medication was given secondary to myocardial infarction; this AE is already listed' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 17:58:54
User entered 'WORSENING OF CARDIOVASCULAR DISEASE/SECONDARY TO MYOCARDIAL INFARCTION' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 17:58:49
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 16:12:37
User entered 'worsening of cardiovascular disease'	Brandon Illickal (b) (4)	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '90'	(b) (4) Brandon Illickal (b) (4)	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'mg (mg)'	(b) (4) Brandon Illickal (b) (4)	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4)	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'twice daily (BID)'	(b) (4) Brandon Illickal (b) (4)	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4)	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Oral (ORAL)'	(b) (4) Brandon Illickal (b) (4)	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered empty.	(b) (4)	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '28 Oct 2020'	(b) (4)	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '0'	(b) (4) Brandon Illickal (b) (4)	16 Mar 2021 22:27:21

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:25:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '26 Nov 2020'	(b) (4)	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'No (N)'	(b) (4)	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User entered '2'	System	16 Mar 2021 22:27:21

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User entered '1'	System	16 Mar 2021 22:27:21

**US3392120**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:25:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:43:27
User entered '804 (804)'	System	16 Mar 2021 22:27:21

US3392120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:25:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:25:17
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered 'Yes (Y)'	(b) (4)	02 Nov 2020 23:00:03

US3392120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:25:38

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered '26 Oct 2020'	Brandon Illickal (b) (4)	02 Nov 2020 23:00:34

US3392120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:25:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'Percutaneous transluminal coronary angioplasty, RIGHT CORONARY ARTERY' reason for change: Data Entry Error	Brandon Illickal (b) (4)	06 Nov 2020 19:52:37
User entered 'stent placement, right coronary artery'	Brandon Illickal (b) (4)	02 Nov 2020 23:00:34

US3392120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:25:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered 'Adverse Event (AE)'	Brandon Illickal (b) (4)	02 Nov 2020 23:00:34

US3392120

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:25:38

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	02 Nov 2020 23:00:34

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered		
'USA-US119-2020-MRNA-1273-P301000006'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Yes (Y)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Yes (Y)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Michael'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Cotugno'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:28:05
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:27:36
User entered 'US'	System	03 Nov 2020 19:54:11

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	17 Mar 2021 19:36:50
User entered '3'	System	30 Nov 2020 15:07:35
User entered '2'	System	17 Nov 2020 13:28:14
User entered '1'	System	03 Nov 2020 19:54:11

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered		
'USA-US119-2020-MRNA-1273-P301000006'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Yes (Y)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Yes (Y)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Michael'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Cotugno'	System	03 Nov 2020 19:53:26

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:28:05
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:27:36
User entered 'US'	System	03 Nov 2020 19:54:11

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	17 Mar 2021 19:36:50
User entered '3'	System	30 Nov 2020 15:07:35
User entered '2'	System	17 Nov 2020 13:28:14
User entered '1'	System	03 Nov 2020 19:54:11

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:25:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:27:36
User entered '03/Nov/2020 19:54'	System	03 Nov 2020 19:54:11

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:25:38

**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 20:05:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:28:05
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:27:36
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 19:54:11

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'USA-US119-2020-MRNA-1273-P301000006'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Yes (Y)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Yes (Y)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Michael'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Cotugno'	System	03 Nov 2020 19:53:26

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:28:05
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:27:36
User entered 'US'	System	03 Nov 2020 19:54:11

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	17 Mar 2021 19:36:50
User entered '3'	System	30 Nov 2020 15:07:35
User entered '2'	System	17 Nov 2020 13:28:14
User entered '1'	System	03 Nov 2020 19:54:11

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:25:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '17/Nov/2020 08:28'	(b) (4) System	17 Nov 2020 13:28:14

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:25:38

**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 20:05:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 15:07:24
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 13:28:14

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered		
'USA-US119-2020-MRNA-1273-P301000006'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Yes (Y)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Yes (Y)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Michael'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Cotugno'	System	03 Nov 2020 19:53:26

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:28:05
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:27:36
User entered 'US'	System	03 Nov 2020 19:54:11

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	17 Mar 2021 19:36:50
User entered '3'	System	30 Nov 2020 15:07:35
User entered '2'	System	17 Nov 2020 13:28:14
User entered '1'	System	03 Nov 2020 19:54:11

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:25:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '30/Nov/2020 15:07'	(b) (4) System	30 Nov 2020 15:07:35

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:25:38

**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 20:05:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 15:07:35

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered		
'USA-US119-2020-MRNA-1273-P301000006'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Yes (Y)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Yes (Y)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'No (N)'	System	03 Nov 2020 19:53:26

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Michael'	System	03 Nov 2020 19:53:26

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 21:27:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:54:05
User entered 'Cotugno'	System	03 Nov 2020 19:53:26

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 13:28:05
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:27:36
User entered 'US'	System	03 Nov 2020 19:54:11

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	17 Mar 2021 19:36:50
User entered '3'	System	30 Nov 2020 15:07:35
User entered '2'	System	17 Nov 2020 13:28:14
User entered '1'	System	03 Nov 2020 19:54:11

**US3392120**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:25:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:05:55
User entered '17/Mar/2021 12:36'	(b) (4) System	17 Mar 2021 19:36:50

US3392120

Folder: SAE USA-US119-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:25:38

**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 20:05:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:36:50