

US3372092 (Prod: Palm Beach Research Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:37:49

All time stamps listed in this document are displayed in GMT

US3372092

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

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[Participant ID](#)

US3372092

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

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US3372092

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:34:30

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Date of Birth (MMM yyyy)	(b) (6) 1952
Age	68
Age Units	YEARS
Age (Derived)	68
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:34:30

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:34:30

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:34:30

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:34:30

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:34:30

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Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:34:30

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Condition	VARICOSE VEINS LEFT LEG
Start date (dd MMM yyyy)	06 JAN 2020
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)	06 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Condition	VARICOSE REMOVAL LEFT LEG
Start date (dd MMM yyyy)	06 JAN 2020
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)	06 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Condition	VARICOSE VEINS RIGHT LEG
Start date (dd MMM yyyy)	06 JAN 2020
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)	06 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Condition	VARICOSE VEIN REMOVAL RIGHT LEG
Start date (dd MMM yyyy)	06 JAN 2020
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)	06 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	17:00 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 17:00
Height (xxx.x)	172.7 cm
Weight (xxx.x)	76.7 kg
BMI (xxx.x)	25.71643 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	36.3 C
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)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:34:30

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:34:30

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** True

**Resides in Nursing Home or Assisted Living Facility** False



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:34:30

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:34:30

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What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 186866

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:34:30

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Height	172.7 cm
Weight	76.5 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Height	172.7 cm
Weight	76.5 kg
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)	19 AUG 2020
Time of assessment (00:00-23:59)	08:48 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 08:48
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Height	172.7 cm
Weight	76.5 kg
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)	19 AUG 2020
Time of assessment (00:00-23:59)	10:18 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 10:18
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 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) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 09:45 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 09:45

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 AUG 2020

Collection time (00:00-23:59)

09:09 (24 HR)

Collection date and time (derived)

19 AUG 2020 09:09

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:08	19 AUG 2020 09:08
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

**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

97.5 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 19 AUG 2020 10:24

PC Open Date & Time 19 AUG 2020 10:05

PC Close Date & Time 19 AUG 2020 12:35

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp	19 AUG 2020 18:29
PC Open Date & Time	19 AUG 2020 13:30
PC Close Date & Time	20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 18:35

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:49

**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

97.5 °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

21 AUG 2020 19:21

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 18:30

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 18:54

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 18:14

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:49

---

**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

25 AUG 2020 20:10

---

PC Open Date & Time

25 AUG 2020 12:00

---

PC Close Date & Time

26 AUG 2020 11:59

---

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 10:24

PC Open Date & Time

19 AUG 2020 10:05

PC Close Date & Time

19 AUG 2020 12:35

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

**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

19 AUG 2020 18:32

PC Open Date & Time

19 AUG 2020 13:30

PC Close Date & Time

20 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:49

**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

20 AUG 2020 18:35

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:49

**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

21 AUG 2020 19:21

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:49

**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

22 AUG 2020 18:31

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59



US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:49

**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

23 AUG 2020 18:55

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:49

**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

24 AUG 2020 18:15

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 7
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	25 AUG 2020 20:10
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

**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 ☐

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 10:25
PC Open Date & Time	19 AUG 2020 10:05
PC Close Date & Time	19 AUG 2020 12:35

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

**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 ☐

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 18:33
PC Open Date & Time	19 AUG 2020 13:30
PC Close Date & Time	20 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:49

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 18:36
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:49

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 19:22
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:49

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 18:31
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 1846

EAB) (1725)

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:49

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 18:56
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:49

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 18:15
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:49

**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 ☒

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:49

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 20:11
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3372092

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372092

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372092

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3372092

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:34:31

Generated On: 11 Aug 2021 22:37:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:34:31

Generated On: 11 Aug 2021 22:37:49

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)	18 SEP 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 09:10
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:34:31

Generated On: 11 Aug 2021 22:37:49

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3372092

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:34:31

Generated On: 11 Aug 2021 22:37:49

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

18 SEP 2020

---

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

---

US3372092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:34:31

Generated On: 11 Aug 2021 22:37:49

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?

What was the treatment date? (dd MMM yyyy)

What was the treatment time? (00:00-23:59)

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3372092

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:34:31

Generated On: 11 Aug 2021 22:37:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 SEP 2020
Collection time (00:00-23:59)	09:38 (24 HR)
Collection date and time (derived)	18 SEP 2020 09:38

US3372092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:35	18 SEP 2020 09:35
Nasopharyngeal Swab 2	No		



US3372092

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:31

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

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

US3372092

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

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

US3372092

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

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

US3372092

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:34:31

Generated On: 11 Aug 2021 22:37:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3



US3372092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:34:31

Generated On: 11 Aug 2021 22:37:49

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) \_\_\_\_\_

US3372092

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:34:31

Generated On: 11 Aug 2021 22:37:49

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.*

US3372092

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:34:31

Generated On: 11 Aug 2021 22:37:49

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

09:27 (24 HR)

Collection date and time (derived)

14 OCT 2020 09:27

US3372092

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:31

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3372092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59



US3372092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3372092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

---

24 NOV 2020 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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 <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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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01 DEC 2020 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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08 DEC 2020 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2020 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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 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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	18 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 DEC 2020 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2020 23:59
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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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 <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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JAN 2021 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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



US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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="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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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02 FEB 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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="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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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="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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

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26 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAR 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 208

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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

23 MAR 2021 14:30:04

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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

30 MAR 2021 14:51:40

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59



US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

<b>TIMEPOINT</b>	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	05 APR 2021 11:19:53
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 08:58:13
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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

16 APR 2021 08:54:30

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 08:41:35

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 271

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59



US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	18 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUN 2021 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

23 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59



US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 362

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	13 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2021 23:59
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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59



US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 390

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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15 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 OCT 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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



US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	29 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 NOV 2021 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

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12 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 NOV 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59



US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

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26 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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07 DEC 2021 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 DEC 2021 23:59



US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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°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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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°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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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18 JAN 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

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21 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JAN 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

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28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

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11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 FEB 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 551

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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



US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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°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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 MAR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 MAR 2022 23:59
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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59



US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐  
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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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15 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 APR 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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07 JUN 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

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17 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59



US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2022 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59



US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

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

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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="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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

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12 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 AUG 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	26 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2022 23:59
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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

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

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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06 SEP 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Close Date & Time](#)

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20 SEP 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**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 ☐

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

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[Patient Cloud Open Date & Time](#)

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07 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2022 23:59

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US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	14 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2022 23:59

US3372092

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

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"/>

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	21 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59



US3372092

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:37:49

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		23 MAR 2021 14:30:49

US3372092

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372092

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372092

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372092

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3372092

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 21:30:40

Generated On: 11 Aug 2021 22:37:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3372092

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 13:16:07

Generated On: 11 Aug 2021 22:37:49

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) \_\_\_\_\_

US3372092

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 21:32:21

Generated On: 11 Aug 2021 22:37:49

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.*

US3372092

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 21:44:44

Generated On: 11 Aug 2021 22:37:49

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

14:40 (24 HR)

Collection date and time (derived)

23 MAR 2021 14:40

US3372092

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 21:44:44

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 17 Apr 2021 19:18:45

Generated On: 11 Aug 2021 22:37:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372092

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 17 Apr 2021 19:18:45

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3372092**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

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*

**US3372092**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372092

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:37:49

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

**US3372092**

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

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

**Generated On: 11 Aug 2021 22:37:49**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3372092

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

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

Visit date (dd MMM yyyy)	26 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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US3372092

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

Form: Unblinding

Data signed: (b) (4) 16 Mar 2021 16:27:43

Generated On: 11 Aug 2021 22:37:49

Date of updated informed consent ( <i>dd MMM yyyy</i> )	26 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	26 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3372092

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Mar 2021 16:28:21

Generated On: 11 Aug 2021 22:37:49

Height	
Weight	
BMI (xxx.x)	

US3372092

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Mar 2021 16:28:21

Generated On: 11 Aug 2021 22:37:49

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 14:30
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG



US3372092

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Mar 2021 16:28:21

Generated On: 11 Aug 2021 22:37:49

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	16:35 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 16:35
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3372092

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

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 16:27:43

Generated On: 11 Aug 2021 22:37:49

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.*

US3372092

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

Form: Exposure

Data signed: (b) (4) 16 Mar 2021 16:27:43

Generated On: 11 Aug 2021 22:37:49

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 JAN 2021

What was the treatment time? (00:00-23:59) 15:03 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 15:03

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

US3372092

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

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

Collection date (dd MMM yyyy)	26 JAN 2021
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Collection time (00:00-23:59)	14:05 (24 HR)
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Collection date and time (derived)	26 JAN 2021 14:05
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US3372092

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00 - 23:59)	14:03
Collection Date and Time (derived)	26 JAN 2021 14:03

US3372092

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372092

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

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



US3372092

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 15:14:46

Generated On: 11 Aug 2021 22:37:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 15:14:46

Generated On: 11 Aug 2021 22:37:49

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)	23 FEB 2021
Time of assessment (00:00-23:59)	14:31 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 14:31
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 15:14:46

Generated On: 11 Aug 2021 22:37:49

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)	23 FEB 2021
Time of assessment (00:00-23:59)	15:28 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 15:28
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3372092

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 15:14:46

Generated On: 11 Aug 2021 22:37:49

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.*

US3372092

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 15:14:46

Generated On: 11 Aug 2021 22:37:49

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 23 FEB 2021

What was the treatment time? (00:00-23:59) 14:58 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 14:58

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

What was the frequency of the study treatment dosing? ONCE

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

US3372092

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 15:14:46

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372092

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 16:28:21

Generated On: 11 Aug 2021 22:37:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372092

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 16:28:21

Generated On: 11 Aug 2021 22:37:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3372092

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 21:48:13

Generated On: 11 Aug 2021 22:37:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3372092

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Mar 2021 21:48:13

Generated On: 11 Aug 2021 22:37:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	23 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	14:21 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 14:21
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse ( <i>xxx</i> )	70 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372092

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 21:48:13

Generated On: 11 Aug 2021 22:37:49

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.*

US3372092

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 21:48:13

Generated On: 11 Aug 2021 22:37:49

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

14:40 (24 HR)

Collection date and time (derived)

23 MAR 2021 14:40

US3372092

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Feb 2021 20:14:44

Generated On: 11 Aug 2021 22:37:49

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Mar 2021 15:58:07

Generated On: 11 Aug 2021 22:37:49

AEID	USA-US056-2021-MRNA-1273-P30 1000011
Adverse event	COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	19 AUG 2020
Start time (00:00-23:59)	10:14 (24 HR)
AE start date and time (derived)	19 AUG 2020 10:14
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	31 AUG 2020
End time (00:00-23:59)	10:14 (24 HR)
AE End Date and Time (derived)	31 AUG 2020 10:14
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"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Mar 2021 15:58:07

Generated On: 11 Aug 2021 22:37:49

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 checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
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)	

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

	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 UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 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 (3)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

	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 UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2005		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Feb 2021 17:34:29

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Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication DIETARY SUPPLEMENT

Dose per administration 5000

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) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

	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 AUG 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

Name of Medication COENZYME Q10

Prophylaxis Yes ☒  
No ☐

Indication DIETARY SUPPLEMENT

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 (5)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

	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 UNK 2017	
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) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA  
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN OCT 2019
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

Name of Medication SHINGRIX

Prophylaxis Yes ☒  
No ☐

Indication HERPES ZOSTER  
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

Name of Medication PNEUMOCOCCAL VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PNEUMONIA  
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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)	09 AUG 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 AUG 2017
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

Name of Medication TETANUS VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFECTION  
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

	Intraocular	<input type="radio"/>
	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)	20 SEP 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 SEP 2011
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Feb 2021 17:34:29

Generated On: 11 Aug 2021 22:37:49

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

US3372092

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 17:34:30

Generated On: 11 Aug 2021 22:37:49

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3372092

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 23 Feb 2021 21:49:48

Generated On: 11 Aug 2021 22:37:49

Date of dosing discontinuation (dd MMM yyyy) 18 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

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

US3372092

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:37:49

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 ☐

US3372092

Folder: SAE USA-US056-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 24 Mar 2021 15:58:07

Generated On: 11 Aug 2021 22:37:49

SAEID	USA-US056-2021-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2



US3372092

Folder: SAE USA-US056-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Mar 2021 15:58:07

Generated On: 11 Aug 2021 22:37:49

SAEID	USA-US056-2021-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	18/MAR/2021 17:07
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

US3372092

Folder: SAE USA-US056-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Mar 2021 15:58:07

Generated On: 11 Aug 2021 22:37:49

SAEID	USA-US056-2021-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	24/MAR/2021 10:52
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

US3372092 (Prod: Palm Beach Research Center)

**US3372092**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:37:49**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'US3372092'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:59:22

US3372092

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:37:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:16:27

**US3372092**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:59:22

US3372092

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Clinic (Clinic)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:16:27

**US3372092**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'SCRN'	System	14 Aug 2020 21:16:27



US3372092

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:37:49

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered (b) (6) 1952'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:59:23

**US3372092**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:49**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '68'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:31:53

**US3372092**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:49**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'YEARS'	System	14 Aug 2020 21:31:53

**US3372092**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:49**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered '68'	System	14 Aug 2020 21:32:30

**US3372092**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:49**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Male (M)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:31:53

**US3372092**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:49**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Peter Jacob (b) (4)	14 Aug 2020 21:31:53

**US3372092**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:49**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'I'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:31:53

**US3372092**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:49**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:31:53



**US3372092**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:49**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:31:53

**US3372092**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:49**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:31:53

**US3372092**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:49**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:31:53

**US3372092**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:49**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:31:53

**US3372092**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:49**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:31:53

**US3372092**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:49**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:31:53

**US3372092**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:37:49**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	Peter Jacob (b) (4)	14 Aug 2020 21:31:53

US3372092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:37:49

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '11 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:32:30



US3372092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'Aug 2020'	System	14 Aug 2020 21:32:30

**US3372092**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered '2020'	System	14 Aug 2020 21:32:30

**US3372092**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:49**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Amendment 1 (1)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:32:30

US3372092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:32:30

**US3372092**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:49**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:32:30

**US3372092**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:49**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:32:30

US3372092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:37:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:32:30

**US3372092**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:37:49**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:59:22



US3372092

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:37:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'I'	System	14 Aug 2020 21:32:34

US3372092

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:32:34

US3372092

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:37:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Aug 2020 21:32:49

US3372092

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:37:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 14:46:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 14:46:43
Data point term sent to Coder	System	02 Oct 2020 14:45:24
User entered 'hypertension'	Peter Jacob (b) (4)	02 Oct 2020 14:45:22

**US3372092**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'un UNK 2015'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:45:22

**US3372092**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:45:22

**US3372092**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 14:45:22

**US3372092**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:49**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:45:22



**US3372092**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:45:22

**US3372092**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'Jan 2015'	System	02 Oct 2020 14:45:22

**US3372092**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered '2015'	System	02 Oct 2020 14:45:22

**US3372092**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered empty.	System	02 Oct 2020 14:45:22

**US3372092**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered empty.	System	02 Oct 2020 14:45:22

US3372092

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:37:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 14:47:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 14:47:45
Data point term sent to Coder	System	02 Oct 2020 14:46:25
User entered 'hypercholesterolemia'	Peter Jacob (b) (4)	02 Oct 2020 14:45:34

**US3372092**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'un UNK 2005'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:45:34

**US3372092**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:45:34



**US3372092**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 14:45:34

**US3372092**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:49**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:45:34

**US3372092**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:45:34

**US3372092**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'Jan 2005'	System	02 Oct 2020 14:45:34

**US3372092**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered '2005'	System	02 Oct 2020 14:45:34

**US3372092**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered empty.	System	02 Oct 2020 14:45:34

**US3372092**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered empty.	System	02 Oct 2020 14:45:34

US3372092

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:37:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User closed query 'Per DM CLR: Please review the start date of this MH as there was a noted procedure of MH #4 VARICOSE REMOVAL LEFT LEG done last 06 JAN 2020 that matches this condition. Note that associated conditions usually occur prior the start date of procedure. Please correct dates or provide explanation for the Med History dates. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:22:23
Query 'Per DM CLR: Please review the start date of this MH as there was a noted procedure of MH #4 VARICOSE REMOVAL LEFT LEG done last 06 JAN 2020 that matches this condition. Note that associated conditions usually occur prior the start date of procedure. Please correct dates or provide explanation for the Med History dates. ' answered with 'patient was diagnosed and had procedure same day, there is no way to know the exact start date of this condition. the date here is the date of diagnosis which was done same day as the procedure.' (Site from DM).	Peter Jacob (b) (4) (b) (4)	07 Nov 2020 00:43:00
User opened query 'Per DM CLR: Please review the start date of this MH as there was a noted procedure of MH #4 VARICOSE REMOVAL LEFT LEG done last 06 JAN 2020 that matches this condition. Note that associated conditions usually occur prior the start date of procedure. Please correct dates or provide explanation for the Med History dates. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:00:16
User coded data point as SOC: Vascular disorders, HLGT: Venous varices, HLT: Varicose veins NEC, PT: Varicose vein, LLT: Varicose veins of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 14:47:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 14:47:45
Data point term sent to Coder	System	02 Oct 2020 14:46:25
User entered 'varicose veins left leg'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:45:56



**US3372092**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '06 Jan 2020'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 14:45:56

**US3372092**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:37:49**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:45:56

**US3372092**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:37:49**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:45:56

**US3372092**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:37:49**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '06 Jan 2020'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 14:45:56

**US3372092**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:37:49**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:45:56

**US3372092**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'Jan 2020'	System	02 Oct 2020 14:45:56

**US3372092**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered '2020'	System	02 Oct 2020 14:45:56

**US3372092**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'Jan 2020'	System	02 Oct 2020 14:45:56



**US3372092**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered '2020'	System	02 Oct 2020 14:45:56

US3372092

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:37:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Venous therapeutic procedures, PT: Varicose vein operation, LLT: Varicose vein operation - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 08:02:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 08:02:42
Data point term sent to Coder	System	02 Oct 2020 14:46:25
User entered 'varicose removal left leg'	Peter Jacob (b) (4)	02 Oct 2020 14:46:16

**US3372092**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '06 Jan 2020'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 14:46:16

**US3372092**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:46:16

**US3372092**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 14:46:16

**US3372092**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:37:49**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '06 Jan 2020'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 14:46:16

**US3372092**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:46:16

**US3372092**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'Jan 2020'	System	02 Oct 2020 14:46:16



**US3372092**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered '2020'	System	02 Oct 2020 14:46:16

**US3372092**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'Jan 2020'	System	02 Oct 2020 14:46:16

**US3372092**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered '2020'	System	02 Oct 2020 14:46:16

US3372092

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:37:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User closed query 'Per DM CLR: Please review the start date of this MH as there was a noted procedure of MH #6 VARICOSE REMOVAL RIGHT LEG done last 06 JAN 2020 that matches this condition. Note that associated conditions usually occur prior the start date of procedure. Please correct dates or provide explanation for the Med History dates. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:22:47
Query 'Per DM CLR: Please review the start date of this MH as there was a noted procedure of MH #6 VARICOSE REMOVAL RIGHT LEG done last 06 JAN 2020 that matches this condition. Note that associated conditions usually occur prior the start date of procedure. Please correct dates or provide explanation for the Med History dates. ' answered with 'diagnosis was same day as procedure ' (Site from DM).	Peter Jacob (b) (4) (b) (4)	07 Nov 2020 00:43:21
User opened query 'Per DM CLR: Please review the start date of this MH as there was a noted procedure of MH #6 VARICOSE REMOVAL RIGHT LEG done last 06 JAN 2020 that matches this condition. Note that associated conditions usually occur prior the start date of procedure. Please correct dates or provide explanation for the Med History dates. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:00:28
User coded data point as SOC: Vascular disorders, HLGT: Venous varices, HLT: Varicose veins NEC, PT: Varicose vein, LLT: Varicose veins of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 14:57:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 14:57:51
Data point term sent to Coder	System	02 Oct 2020 14:56:48
User entered 'varicose veins right leg'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:56:40

**US3372092**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '06 Jan 2020'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 14:56:40

**US3372092**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:37:49**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 14:56:40

**US3372092**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:37:49**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 14:56:40

**US3372092**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:37:49**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '06 Jan 2020'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 14:56:40



**US3372092**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:37:49**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 14:56:40

**US3372092**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'Jan 2020'	System	02 Oct 2020 14:56:40

**US3372092**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered '2020'	System	02 Oct 2020 14:56:40

**US3372092**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'Jan 2020'	System	02 Oct 2020 14:56:40

**US3372092**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered '2020'	System	02 Oct 2020 14:56:40

US3372092

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:37:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Venous therapeutic procedures, PT: Varicose vein operation, LLT: Varicose vein operation - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 15:01:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 15:01:49
Data point term sent to Coder	System	02 Oct 2020 15:00:54
User entered 'varicose vein removal right leg'	Peter Jacob (b) (4)	02 Oct 2020 15:00:35

**US3372092**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '06 Jan 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:00:35

US3372092

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:37:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:00:35



**US3372092**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:37:49**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:00:35

**US3372092**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:37:49**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '06 Jan 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:00:35

**US3372092**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:37:49**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:00:35

**US3372092**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'Jan 2020'	System	02 Oct 2020 15:00:35

**US3372092**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered '2020'	System	02 Oct 2020 15:00:35

**US3372092**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'Jan 2020'	System	02 Oct 2020 15:00:35

**US3372092**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered '2020'	System	02 Oct 2020 15:00:35

**US3372092**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:41:39



US3372092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '11 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:41:39

**US3372092**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '17:00'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:41:39

**US3372092**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered '11 Aug 2020 17:00'	System	02 Oct 2020 15:41:39

US3372092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '172.7' cm	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:41:39
DataPoint set to visible.	(b) (4) System	14 Aug 2020 21:32:34

**US3372092**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '76.7' kg	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:41:39
DataPoint set to visible.	(b) (4) System	14 Aug 2020 21:32:34

US3372092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered '25.71643'	System	02 Oct 2020 15:41:39
DataPoint set to visible.	System	14 Aug 2020 21:32:34

US3372092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'kg/m2'	System	02 Oct 2020 15:41:39
DataPoint set to visible.	System	14 Aug 2020 21:32:34

US3372092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '36.3' C	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:41:39



US3372092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:41:39

**US3372092**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:41:39

**US3372092**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '68'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:41:39

**US3372092**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'bpm'	System	02 Oct 2020 15:41:39

US3372092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '10'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:41:39

US3372092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'breaths/min'	System	02 Oct 2020 15:41:39

US3372092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '134'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:41:39

US3372092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'mmHg'	System	02 Oct 2020 15:41:39



US3372092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '76'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:41:39

US3372092

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered 'mmHg'	System	02 Oct 2020 15:41:39

**US3372092**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 12:30:01

**US3372092**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01

US3372092

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:41:47

US3372092

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '11 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:41:47

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55



US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55



US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'I'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55



US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

US3372092

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:37:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:25:55

**US3372092**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:16:36

US3372092

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:37:49

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '19 Aug 2020'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:16:36

US3372092

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Clinic (Clinic)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:16:36

**US3372092**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'VISIT1'	System	19 Aug 2020 13:16:36

US3372092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 13:20:13



US3372092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:37:49

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:42:12
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:42:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 13:20:13
User entered '186866' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 13:20:13

US3372092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 13:20:13

US3372092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:17:22

US3372092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:17:22

US3372092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:17:22

**US3372092**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:37:49**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:17:22

US3372092

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:37:49

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:17:22

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '172.7' cm	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:47:20



US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '76.5' kg	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '172.7' cm	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '76.5' kg	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '19 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:47:20

**US3372092**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '08:48'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered '19 Aug 2020 08:48'	System	02 Oct 2020 15:47:20



US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '36.3' C	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '62'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'bpm'	System	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '18'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'breaths/min'	System	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '118'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:47:20



US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'mmHg'	System	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '65'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'mmHg'	System	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '172.7' cm	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '76.5' kg	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:47:20

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:48:02

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:48:02

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '19 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:48:02



US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '10:18'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:48:02

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered '19 Aug 2020 10:18'	System	02 Oct 2020 15:48:02

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '36.4' C	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:48:02

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:48:02

**US3372092**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:48:02

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '58'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:48:02

**US3372092**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'bpm'	System	02 Oct 2020 15:48:02

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '18'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:48:02



US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'breaths/min'	System	02 Oct 2020 15:48:02

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '115'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:48:02

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'mmHg'	System	02 Oct 2020 15:48:02

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '75'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:48:02

US3372092

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'mmHg'	System	02 Oct 2020 15:48:02

**US3372092**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:49**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:48:11

**US3372092**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:49**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '19 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:48:11

US3372092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:48:05



US3372092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:48:05

US3372092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:48:05

US3372092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 13:48:05

US3372092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '19 Aug 2020'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:48:05

US3372092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '09:45'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:48:05

US3372092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered '19 Aug 2020 09:45'	System	19 Aug 2020 13:48:05

US3372092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Mary Sergalis (b) (4)	19 Aug 2020 13:48:05

US3372092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'ONCE'	System	19 Aug 2020 13:48:05



US3372092

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 13:48:05

US3372092

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:48:27

US3372092

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '19 Aug 2020'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:48:27

**US3372092**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:49**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '09:09' reason for change: Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	02 Oct 2020 15:48:49
User entered '09:08'	(b) (4)	
	Peter Jacob (b) (4)	02 Oct 2020 15:48:27
	(b) (4)	

US3372092

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered '19 Aug 2020 09:09'	System	02 Oct 2020 15:48:49
User entered '19 Aug 2020 09:08'	System	02 Oct 2020 15:48:27

**US3372092**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:37:49**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '19 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:48:39

US3372092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:37:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:48:39

US3372092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:37:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:48:39



US3372092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:37:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '09:08'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:48:39

**US3372092**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered '19 Aug 2020 09:08'	System	02 Oct 2020 15:48:39

US3372092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:37:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:48:39

US3372092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:37:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:48:39

**US3372092**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:37:49**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:48:39

US3372092

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:37:49

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered empty.	System	02 Oct 2020 15:48:39

US3372092

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	27 Aug 2020 17:20:38

**US3372092**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'I'	System	27 Aug 2020 17:20:38



US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:23:41', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '9bc0588d-9f9d-4247-b015-696de840917c' User entered 'Yes (Y)'	System	19 Aug 2020 14:24:24
	System	19 Aug 2020 14:24:24

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:24:12', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '9bc0588d-9f9d-4247-b015-696de840917c' User entered '97.5'	System	19 Aug 2020 14:24:24
	System	19 Aug 2020 14:24:24

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:24:17', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '9bc0588d-9f9d-4247-b015-696de840917c' User entered 'No (N)'	System	19 Aug 2020 14:24:24
	System	19 Aug 2020 14:24:24

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:24:22', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '9bc0588d-9f9d-4247-b015-696de840917c' User entered '19 Aug 2020 10:24'	System	19 Aug 2020 14:24:24
	System	19 Aug 2020 14:24:24

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '19 Aug 2020 10:05'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '19 Aug 2020 12:35'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 13:48:05



US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:29:15', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '09c19f56-40fc-4421-b7e5-24a4a0bee67f' User entered 'Yes (Y)'	System	19 Aug 2020 22:29:47
	System	19 Aug 2020 22:29:47

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:29:23', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '09c19f56-40fc-4421-b7e5-24a4a0bee67f' User entered '97.2'	System	19 Aug 2020 22:29:47
	System	19 Aug 2020 22:29:47

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:29:33', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '09c19f56-40fc-4421-b7e5-24a4a0bee67f' User entered 'No (N)'	System	19 Aug 2020 22:29:47
	System	19 Aug 2020 22:29:47

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:29:45', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '09c19f56-40fc-4421-b7e5-24a4a0bee67f' User entered '19 Aug 2020 18:29'	System	19 Aug 2020 22:29:47
	System	19 Aug 2020 22:29:47

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '19 Aug 2020 13:30'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 2'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:34:39', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '410ddd7-fe21-4456-a876-8f0eebb00dac' User entered 'Yes (Y)'	System	20 Aug 2020 22:35:16
	System	20 Aug 2020 22:35:16



US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:35:04', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '410ddd7-fe21-4456-a876-8f0eebb00dac' User entered '97.7'	System	20 Aug 2020 22:35:16
	System	20 Aug 2020 22:35:16

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:35:08', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '410ddd7-fe21-4456-a876-8f0eebb00dac'	System	20 Aug 2020 22:35:16
User entered 'No (N)'	System	20 Aug 2020 22:35:16

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:35:13', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '410ddd7-fe21-4456-a876-8f0eebb00dac' User entered '20 Aug 2020 18:35'	System	20 Aug 2020 22:35:16
	System	20 Aug 2020 22:35:16

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:37:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 3'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:21:20', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '745a44e9-16f0-4882-80e0-e93a39674481' User entered 'Yes (Y)'	System	21 Aug 2020 23:21:39
	System	21 Aug 2020 23:21:39

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:21:29', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '745a44e9-16f0-4882-80e0-e93a39674481' User entered '97.5'	System	21 Aug 2020 23:21:39
	System	21 Aug 2020 23:21:39



US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:21:34', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '745a44e9-16f0-4882-80e0-e93a39674481' User entered 'No (N)'	System	21 Aug 2020 23:21:39
	System	21 Aug 2020 23:21:39

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:21:38', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '745a44e9-16f0-4882-80e0-e93a39674481' User entered '21 Aug 2020 19:21'	System	21 Aug 2020 23:21:39
	System	21 Aug 2020 23:21:39

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:37:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 4'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:29:56', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '1de8438b-a066-486b-a17e-6711b7658bbe' User entered 'Yes (Y)'	System	22 Aug 2020 22:30:22
	System	22 Aug 2020 22:30:22

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:30:10', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '1de8438b-a066-486b-a17e-6711b7658bbe' User entered '97.8'	System	22 Aug 2020 22:30:22
	System	22 Aug 2020 22:30:22

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:30:16', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '1de8438b-a066-486b-a17e-6711b7658bbe' User entered 'No (N)'	System	22 Aug 2020 22:30:22
	System	22 Aug 2020 22:30:22



**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:30:20', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '1de8438b-a066-486b-a17e-6711b7658bbe' User entered '22 Aug 2020 18:30'	System	22 Aug 2020 22:30:22
	System	22 Aug 2020 22:30:22

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:37:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 5'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:37:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:54:39', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '4cb91287-cb94-4fdf-a523-c2a6e65b8abe' User entered 'Yes (Y)'	System	23 Aug 2020 22:55:11
	System	23 Aug 2020 22:55:11

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:37:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:54:47', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '4cb91287-cb94-4fdf-a523-c2a6e65b8abe' User entered '97.2'	System	23 Aug 2020 22:55:11
	System	23 Aug 2020 22:55:11

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:54:52', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '4cb91287-cb94-4fdf-a523-c2a6e65b8abe'	System	23 Aug 2020 22:55:11
User entered 'No (N)'	System	23 Aug 2020 22:55:11

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:37:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:54:58', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '4cb91287-cb94-4fdf-a523-c2a6e65b8abe' User entered '23 Aug 2020 18:54'	System	23 Aug 2020 22:55:11
	System	23 Aug 2020 22:55:11



**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 6'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:13:56', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '0e4a1b6b-463a-4d96-ab66-b51f4499492a' User entered 'Yes (Y)'	System	24 Aug 2020 22:14:40
	System	24 Aug 2020 22:14:40

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:14:31', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '0e4a1b6b-463a-4d96-ab66-b51f4499492a' User entered '97.4'	System	24 Aug 2020 22:14:40
	System	24 Aug 2020 22:14:40

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:14:34', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '0e4a1b6b-463a-4d96-ab66-b51f4499492a' User entered 'No (N)'	System	24 Aug 2020 22:14:40
	System	24 Aug 2020 22:14:40

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:14:38', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '0e4a1b6b-463a-4d96-ab66-b51f4499492a' User entered '24 Aug 2020 18:14'	System	24 Aug 2020 22:14:40
	System	24 Aug 2020 22:14:40

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 13:48:05



US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:37:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 7'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:09:54', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'bb82e7a7-2c8e-4792-b439-288093df2e1a' User entered 'Yes (Y)'	System	26 Aug 2020 00:10:27
	System	26 Aug 2020 00:10:27

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:10:14', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'bb82e7a7-2c8e-4792-b439-288093df2e1a' User entered '97.9'	System	26 Aug 2020 00:10:27
	System	26 Aug 2020 00:10:27

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:10:19', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'bb82e7a7-2c8e-4792-b439-288093df2e1a'	System	26 Aug 2020 00:10:27
User entered 'No (N)'	System	26 Aug 2020 00:10:27

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:10:23', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'bb82e7a7-2c8e-4792-b439-288093df2e1a' User entered '25 Aug 2020 20:10'	System	26 Aug 2020 00:10:27
	System	26 Aug 2020 00:10:27

US3372092

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:37:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 13:48:05



US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:24:36', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '6a652c77-8ad9-4bc3-baa3-9a3a7a1c3977'	System	19 Aug 2020 14:24:58
User entered 'None (1)'	System	19 Aug 2020 14:24:58

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:24:41', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '6a652c77-8ad9-4bc3-baa3-9a3a7a1c3977'	System	19 Aug 2020 14:24:58
User entered 'No (N)'	System	19 Aug 2020 14:24:58

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:24:45', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '6a652c77-8ad9-4bc3-baa3-9a3a7a1c3977'	System	19 Aug 2020 14:24:58
User entered 'No (N)'	System	19 Aug 2020 14:24:58

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:24:51', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '6a652c77-8ad9-4bc3-baa3-9a3a7a1c3977'	System	19 Aug 2020 14:24:58
User entered 'None (1)'	System	19 Aug 2020 14:24:58

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:24:55', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '6a652c77-8ad9-4bc3-baa3-9a3a7a1c3977' User entered '19 Aug 2020 10:24'	System	19 Aug 2020 14:24:58
	System	19 Aug 2020 14:24:58

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '19 Aug 2020 10:05'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '19 Aug 2020 12:35'	System	19 Aug 2020 13:48:05



US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:30:04', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'b7173201-158e-48f4-9088-08f74cc32ab3'	System	19 Aug 2020 22:32:08
User entered 'None (1)'	System	19 Aug 2020 22:32:08

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:31:35', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'b7173201-158e-48f4-9088-08f74cc32ab3' User entered 'No (N)'	System	19 Aug 2020 22:32:08
	System	19 Aug 2020 22:32:08

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:31:41', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'b7173201-158e-48f4-9088-08f74cc32ab3' User entered 'No (N)'	System	19 Aug 2020 22:32:08
	System	19 Aug 2020 22:32:08

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:31:55', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'b7173201-158e-48f4-9088-08f74cc32ab3'	System	19 Aug 2020 22:32:08
User entered 'None (1)'	System	19 Aug 2020 22:32:08

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:32:06', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'b7173201-158e-48f4-9088-08f74cc32ab3'	System	19 Aug 2020 22:32:08
User entered '19 Aug 2020 18:32'	System	19 Aug 2020 22:32:08

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '19 Aug 2020 13:30'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 13:48:05



US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 2'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:35:21', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'dbc03403-4cc1-4eba-b69f-f4f3c25467ca' User entered 'None (1)'	System	20 Aug 2020 22:35:43
	System	20 Aug 2020 22:35:43

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:35:25', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'dbc03403-4cc1-4eba-b69f-f4f3c25467ca'	System	20 Aug 2020 22:35:43
User entered 'No (N)'	System	20 Aug 2020 22:35:43

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:35:30', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'dbc03403-4cc1-4eba-b69f-f4f3c25467ca' User entered 'No (N)'	System	20 Aug 2020 22:35:43
	System	20 Aug 2020 22:35:43

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:35:38', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'dbc03403-4cc1-4eba-b69f-f4f3c25467ca' User entered 'None (1)'	System	20 Aug 2020 22:35:43
	System	20 Aug 2020 22:35:43

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:35:41', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'dbc03403-4cc1-4eba-b69f-f4f3c25467ca' User entered '20 Aug 2020 18:35'	System	20 Aug 2020 22:35:43
	System	20 Aug 2020 22:35:43

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:37:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 13:48:05



US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 3'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:20:48', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '2cec1a84-acf3-4a03-a307-47b07cc80bf6'	System	21 Aug 2020 23:21:10
User entered 'None (1)'	System	21 Aug 2020 23:21:10

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:20:51', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '2cec1a84-acf3-4a03-a307-47b07cc80bf6'	System	21 Aug 2020 23:21:10
User entered 'No (N)'	System	21 Aug 2020 23:21:10

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:20:58', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '2cec1a84-acf3-4a03-a307-47b07cc80bf6' User entered 'No (N)'	System	21 Aug 2020 23:21:10
	System	21 Aug 2020 23:21:10

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:21:03', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '2cec1a84-acf3-4a03-a307-47b07cc80bf6' User entered 'None (1)'	System	21 Aug 2020 23:21:10
	System	21 Aug 2020 23:21:10

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:21:08', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '2cec1a84-acf3-4a03-a307-47b07cc80bf6' User entered '21 Aug 2020 19:21'	System	21 Aug 2020 23:21:10
	System	21 Aug 2020 23:21:10

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 13:48:05



US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 4'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:30:27', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '38df854d-fe70-4641-8bac-4c15f3731e3b' User entered 'None (1)'	System	22 Aug 2020 22:31:02
	System	22 Aug 2020 22:31:02

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:30:31', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '38df854d-fe70-4641-8bac-4c15f3731e3b' User entered 'No (N)'	System	22 Aug 2020 22:31:02
	System	22 Aug 2020 22:31:02

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:30:36', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '38df854d-fe70-4641-8bac-4c15f3731e3b' User entered 'No (N)'	System	22 Aug 2020 22:31:02
	System	22 Aug 2020 22:31:02

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:30:57', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '38df854d-fe70-4641-8bac-4c15f3731e3b' User entered 'None (1)'	System	22 Aug 2020 22:31:02
	System	22 Aug 2020 22:31:02

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:31:01', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '38df854d-fe70-4641-8bac-4c15f3731e3b' User entered '22 Aug 2020 18:31'	System	22 Aug 2020 22:31:02
	System	22 Aug 2020 22:31:02

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 13:48:05



US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 5'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:55:06', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '075c341a-e625-4a93-b63c-bb9190417577'	System	23 Aug 2020 22:55:42
User entered 'None (1)'	System	23 Aug 2020 22:55:42

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:55:09', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '075c341a-e625-4a93-b63c-bb9190417577'	System	23 Aug 2020 22:55:42
User entered 'No (N)'	System	23 Aug 2020 22:55:42

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:55:13', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '075c341a-e625-4a93-b63c-bb9190417577' User entered 'No (N)'	System	23 Aug 2020 22:55:42
	System	23 Aug 2020 22:55:42

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:55:38', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '075c341a-e625-4a93-b63c-bb9190417577'	System	23 Aug 2020 22:55:42
User entered 'None (1)'	System	23 Aug 2020 22:55:42

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:55:41', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '075c341a-e625-4a93-b63c-bb9190417577'	System	23 Aug 2020 22:55:42
User entered '23 Aug 2020 18:55'	System	23 Aug 2020 22:55:42

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 13:48:05



US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 6'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:14:47', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '89e9c5ce-8402-48f7-918b-c75f9510509e' User entered 'None (1)'	System	24 Aug 2020 22:15:10
	System	24 Aug 2020 22:15:10

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:14:53', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '89e9c5ce-8402-48f7-918b-c75f9510509e' User entered 'No (N)'	System	24 Aug 2020 22:15:10
	System	24 Aug 2020 22:15:10

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:14:55', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '89e9c5ce-8402-48f7-918b-c75f9510509e' User entered 'No (N)'	System	24 Aug 2020 22:15:10
	System	24 Aug 2020 22:15:10

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:15:03', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '89e9c5ce-8402-48f7-918b-c75f9510509e' User entered 'None (1)'	System	24 Aug 2020 22:15:10
	System	24 Aug 2020 22:15:10

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:15:06', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '89e9c5ce-8402-48f7-918b-c75f9510509e' User entered '24 Aug 2020 18:15'	System	24 Aug 2020 22:15:10
	System	24 Aug 2020 22:15:10

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 13:48:05



US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 7'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:10:29', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '60681a69-701a-493a-b3bd-af192e367df7'	System	26 Aug 2020 00:10:44
User entered 'None (1)'	System	26 Aug 2020 00:10:44

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:10:33', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '60681a69-701a-493a-b3bd-af192e367df7'	System	26 Aug 2020 00:10:44
User entered 'No (N)'	System	26 Aug 2020 00:10:44

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:10:36', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '60681a69-701a-493a-b3bd-af192e367df7'	System	26 Aug 2020 00:10:44
User entered 'No (N)'	System	26 Aug 2020 00:10:44

US3372092

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:37:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:10:40', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '60681a69-701a-493a-b3bd-af192e367df7' User entered 'None (1)'	System	26 Aug 2020 00:10:44
	System	26 Aug 2020 00:10:44

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:10:43', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '60681a69-701a-493a-b3bd-af192e367df7'	System	26 Aug 2020 00:10:44
User entered '25 Aug 2020 20:10'	System	26 Aug 2020 00:10:44

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 13:48:05



**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:49**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:25:03', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'd08c2abc-1da0-4e1a-828e-ee5191dd6358' User entered 'None (0)'	System	19 Aug 2020 14:25:30
	System	19 Aug 2020 14:25:30

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:25:07', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'd08c2abc-1da0-4e1a-828e-ee5191dd6358' User entered 'None (0)'	System	19 Aug 2020 14:25:30
	System	19 Aug 2020 14:25:30

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:25:12', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'd08c2abc-1da0-4e1a-828e-ee5191dd6358' User entered 'None (0)'	System	19 Aug 2020 14:25:30
	System	19 Aug 2020 14:25:30

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:25:15', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'd08c2abc-1da0-4e1a-828e-ee5191dd6358' User entered 'None (0)'	System	19 Aug 2020 14:25:30
	System	19 Aug 2020 14:25:30

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:25:18', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'd08c2abc-1da0-4e1a-828e-ee5191dd6358' User entered 'None (0)'	System	19 Aug 2020 14:25:30
	System	19 Aug 2020 14:25:30

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:49**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:25:21', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'd08c2abc-1da0-4e1a-828e-ee5191dd6358' User entered 'None (0)'	System	19 Aug 2020 14:25:30
	System	19 Aug 2020 14:25:30

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:37:49

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)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:25:26', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'd08c2abc-1da0-4e1a-828e-ee5191dd6358'	System	19 Aug 2020 14:25:30
User entered 'No (N)'	System	19 Aug 2020 14:25:30



**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T10:25:29', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'd08c2abc-1da0-4e1a-828e-ee5191dd6358'	System	19 Aug 2020 14:25:30
User entered '19 Aug 2020 10:25'	System	19 Aug 2020 14:25:30

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '19 Aug 2020 10:05'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '19 Aug 2020 12:35'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:49**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:32:18', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '2f40f405-875d-4a51-8085-7178915f71be' User entered 'None (0)'	System	19 Aug 2020 22:33:05
	System	19 Aug 2020 22:33:05

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:32:29', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '2f40f405-875d-4a51-8085-7178915f71be' User entered 'None (0)'	System	19 Aug 2020 22:33:05
	System	19 Aug 2020 22:33:05

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:32:32', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '2f40f405-875d-4a51-8085-7178915f71be' User entered 'None (0)'	System	19 Aug 2020 22:33:05
	System	19 Aug 2020 22:33:05

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:32:36', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '2f40f405-875d-4a51-8085-7178915f71be' User entered 'None (0)'	System	19 Aug 2020 22:33:05
	System	19 Aug 2020 22:33:05



US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:32:40', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '2f40f405-875d-4a51-8085-7178915f71be' User entered 'None (0)'	System	19 Aug 2020 22:33:05
	System	19 Aug 2020 22:33:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:49**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:32:45', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '2f40f405-875d-4a51-8085-7178915f71be' User entered 'None (0)'	System	19 Aug 2020 22:33:05
	System	19 Aug 2020 22:33:05

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:37:49

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)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:32:55', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '2f40f405-875d-4a51-8085-7178915f71be'	System	19 Aug 2020 22:33:05
User entered 'No (N)'	System	19 Aug 2020 22:33:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-19T18:33:01', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '2f40f405-875d-4a51-8085-7178915f71be' User entered '19 Aug 2020 18:33'	System	19 Aug 2020 22:33:05
	System	19 Aug 2020 22:33:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '19 Aug 2020 13:30'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 2'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:49**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:35:48', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'e895417f-d697-44a9-8b92-449b3fc2a1e6' User entered 'None (0)'	System	20 Aug 2020 22:36:17
	System	20 Aug 2020 22:36:17



US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:35:52', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'e895417f-d697-44a9-8b92-449b3fc2a1e6' User entered 'None (0)'	System	20 Aug 2020 22:36:17
	System	20 Aug 2020 22:36:17

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:35:55', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'e895417f-d697-44a9-8b92-449b3fc2a1e6' User entered 'None (0)'	System	20 Aug 2020 22:36:17
	System	20 Aug 2020 22:36:17

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:35:58', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'e895417f-d697-44a9-8b92-449b3fc2a1e6' User entered 'None (0)'	System	20 Aug 2020 22:36:17
	System	20 Aug 2020 22:36:17

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:49

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:36:02', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'e895417f-d697-44a9-8b92-449b3fc2a1e6' User entered 'None (0)'	System	20 Aug 2020 22:36:17
	System	20 Aug 2020 22:36:17

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:49

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:36:07', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'e895417f-d697-44a9-8b92-449b3fc2a1e6' User entered 'None (0)'	System	20 Aug 2020 22:36:17
	System	20 Aug 2020 22:36:17

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:37:49

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)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:36:11', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'e895417f-d697-44a9-8b92-449b3fc2a1e6' User entered 'No (N)'	System	20 Aug 2020 22:36:17
	System	20 Aug 2020 22:36:17

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-20T18:36:14', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'e895417f-d697-44a9-8b92-449b3fc2a1e6' User entered '20 Aug 2020 18:36'	System	20 Aug 2020 22:36:17
	System	20 Aug 2020 22:36:17

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 13:48:05



**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 3'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:21:47', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '307a4569-01e4-441d-99f2-c34adc79259f' User entered 'None (0)'	System	21 Aug 2020 23:22:13
	System	21 Aug 2020 23:22:13

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:21:52', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '307a4569-01e4-441d-99f2-c34adc79259f' User entered 'None (0)'	System	21 Aug 2020 23:22:13
	System	21 Aug 2020 23:22:13

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:21:54', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '307a4569-01e4-441d-99f2-c34adc79259f' User entered 'None (0)'	System	21 Aug 2020 23:22:13
	System	21 Aug 2020 23:22:13

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:21:57', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '307a4569-01e4-441d-99f2-c34adc79259f' User entered 'None (0)'	System	21 Aug 2020 23:22:13
	System	21 Aug 2020 23:22:13

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:49**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:22:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '307a4569-01e4-441d-99f2-c34adc79259f' User entered 'None (0)'	System	21 Aug 2020 23:22:13
	System	21 Aug 2020 23:22:13

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:49

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:22:03', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '307a4569-01e4-441d-99f2-c34adc79259f' User entered 'None (0)'	System	21 Aug 2020 23:22:13
	System	21 Aug 2020 23:22:13



US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:37:49

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)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:22:07', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '307a4569-01e4-441d-99f2-c34adc79259f' User entered 'No (N)'	System	21 Aug 2020 23:22:13
	System	21 Aug 2020 23:22:13

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-21T19:22:10', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '307a4569-01e4-441d-99f2-c34adc79259f' User entered '21 Aug 2020 19:22'	System	21 Aug 2020 23:22:13
	System	21 Aug 2020 23:22:13

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 4'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:49

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:31:09', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'af0f2dbe-f155-4f30-9d7a-8f02c42182fa' User entered 'None (0)'	System	22 Aug 2020 22:31:41
	System	22 Aug 2020 22:31:41

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:31:18', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'af0f2dbe-f155-4f30-9d7a-8f02c42182fa' User entered 'None (0)'	System	22 Aug 2020 22:31:41
	System	22 Aug 2020 22:31:41

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:31:21', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'af0f2dbe-f155-4f30-9d7a-8f02c42182fa' User entered 'None (0)'	System	22 Aug 2020 22:31:41
	System	22 Aug 2020 22:31:41



US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:31:24', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'af0f2dbe-f155-4f30-9d7a-8f02c42182fa' User entered 'None (0)'	System	22 Aug 2020 22:31:41
	System	22 Aug 2020 22:31:41

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:49

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:31:27', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'af0f2dbe-f155-4f30-9d7a-8f02c42182fa' User entered 'None (0)'	System	22 Aug 2020 22:31:41
	System	22 Aug 2020 22:31:41

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:49

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:31:29', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'af0f2dbe-f155-4f30-9d7a-8f02c42182fa' User entered 'None (0)'	System	22 Aug 2020 22:31:41
	System	22 Aug 2020 22:31:41

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:37:49

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)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:31:36', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'af0f2dbe-f155-4f30-9d7a-8f02c42182fa'	System	22 Aug 2020 22:31:41
User entered 'No (N)'	System	22 Aug 2020 22:31:41

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-22T18:31:39', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'af0f2dbe-f155-4f30-9d7a-8f02c42182fa'	System	22 Aug 2020 22:31:41
User entered '22 Aug 2020 18:31'	System	22 Aug 2020 22:31:41

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 5'	System	19 Aug 2020 13:48:05



**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:49**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:55:47', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '65e454a6-82c2-430c-ae8f-93dc3246cca4' User entered 'None (0)'	System	23 Aug 2020 22:56:13
	System	23 Aug 2020 22:56:13

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:55:50', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '65e454a6-82c2-430c-ae8f-93dc3246cca4' User entered 'None (0)'	System	23 Aug 2020 22:56:13
	System	23 Aug 2020 22:56:13

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:55:53', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '65e454a6-82c2-430c-ae8f-93dc3246cca4' User entered 'None (0)'	System	23 Aug 2020 22:56:13
	System	23 Aug 2020 22:56:13

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:55:56', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '65e454a6-82c2-430c-ae8f-93dc3246cca4' User entered 'None (0)'	System	23 Aug 2020 22:56:13
	System	23 Aug 2020 22:56:13

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:49

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:55:58', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '65e454a6-82c2-430c-ae8f-93dc3246cca4' User entered 'None (0)'	System	23 Aug 2020 22:56:13
	System	23 Aug 2020 22:56:13

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:49**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:56:01', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '65e454a6-82c2-430c-ae8f-93dc3246cca4' User entered 'None (0)'	System	23 Aug 2020 22:56:13
	System	23 Aug 2020 22:56:13

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:37:49

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)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:56:08', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '65e454a6-82c2-430c-ae8f-93dc3246cca4' User entered 'No (N)'	System	23 Aug 2020 22:56:13
	System	23 Aug 2020 22:56:13

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-23T18:56:11', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '65e454a6-82c2-430c-ae8f-93dc3246cca4' User entered '23 Aug 2020 18:56'	System	23 Aug 2020 22:56:13
	System	23 Aug 2020 22:56:13



**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 6'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:49**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:15:14', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '0e4fc5dc-f3bc-4717-ae0-52998386c70f' User entered 'None (0)'	System	24 Aug 2020 22:15:40
	System	24 Aug 2020 22:15:40

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:15:17', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '0e4fc5dc-f3bc-4717-ae0-52998386c70f' User entered 'None (0)'	System	24 Aug 2020 22:15:40
	System	24 Aug 2020 22:15:40

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:15:22', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '0e4fc5dc-f3bc-4717-ae0-52998386c70f' User entered 'None (0)'	System	24 Aug 2020 22:15:40
	System	24 Aug 2020 22:15:40

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:15:24', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '0e4fc5dc-f3bc-4717-ae0-52998386c70f' User entered 'None (0)'	System	24 Aug 2020 22:15:40
	System	24 Aug 2020 22:15:40

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:49

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:15:27', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '0e4fc5dc-f3bc-4717-ae0-52998386c70f' User entered 'None (0)'	System	24 Aug 2020 22:15:40
	System	24 Aug 2020 22:15:40



**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:49**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:15:29', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '0e4fc5dc-f3bc-4717-ae0-52998386c70f' User entered 'None (0)'	System	24 Aug 2020 22:15:40
	System	24 Aug 2020 22:15:40

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:37:49

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)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:15:34', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '0e4fc5dc-f3bc-4717-ae0-52998386c70f' User entered 'No (N)'	System	24 Aug 2020 22:15:40
	System	24 Aug 2020 22:15:40

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-24T18:15:38', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '0e4fc5dc-f3bc-4717-ae0-52998386c70f' User entered '24 Aug 2020 18:15'	System	24 Aug 2020 22:15:40
	System	24 Aug 2020 22:15:40

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 13:48:05

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:49

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 7'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:49**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:10:48', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '17504e23-e5a6-49a2-b7fd-03fb5fcd8a7e' User entered 'None (0)'	System	26 Aug 2020 00:11:14
	System	26 Aug 2020 00:11:14

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:49

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:10:51', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '17504e23-e5a6-49a2-b7fd-03fb5fcd8a7e' User entered 'None (0)'	System	26 Aug 2020 00:11:14
	System	26 Aug 2020 00:11:14



US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:49

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:10:53', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '17504e23-e5a6-49a2-b7fd-03fb5fcd8a7e' User entered 'None (0)'	System	26 Aug 2020 00:11:14
	System	26 Aug 2020 00:11:14

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:49

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:10:56', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '17504e23-e5a6-49a2-b7fd-03fb5fcd8a7e' User entered 'None (0)'	System	26 Aug 2020 00:11:14
	System	26 Aug 2020 00:11:14

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:49

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:10:58', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '17504e23-e5a6-49a2-b7fd-03fb5fcd8a7e' User entered 'None (0)'	System	26 Aug 2020 00:11:14
	System	26 Aug 2020 00:11:14

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:49**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:11:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '17504e23-e5a6-49a2-b7fd-03fb5fcd8a7e' User entered 'None (0)'	System	26 Aug 2020 00:11:14
	System	26 Aug 2020 00:11:14

US3372092

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:37:49

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)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:11:06', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '17504e23-e5a6-49a2-b7fd-03fb5fcd8a7e' User entered 'No (N)'	System	26 Aug 2020 00:11:14
	System	26 Aug 2020 00:11:14

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2020-08-25T20:11:09', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '17504e23-e5a6-49a2-b7fd-03fb5fcd8a7e' User entered '25 Aug 2020 20:11'	System	26 Aug 2020 00:11:14
	System	26 Aug 2020 00:11:14

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 13:48:05

**US3372092**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:37:49**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:28:51
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 13:48:05



**US3372092**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	27 Aug 2020 17:20:54

**US3372092**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '26 Aug 2020'	(b) (4) Alexandra Arango (b) (4)	27 Aug 2020 17:20:54

**US3372092**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	27 Aug 2020 17:20:54

US3372092

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Alexandra Arango (b) (4)	27 Aug 2020 17:20:54
	(b) (4)	

US3372092

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	27 Aug 2020 17:20:57

**US3372092**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'I'	System	27 Aug 2020 17:20:57

**US3372092**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 19:25:39

**US3372092**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '2 Sep 2020'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 19:25:39



**US3372092**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 19:25:39

US3372092

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 19:25:39
	(b) (4)	

US3372092

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 19:25:43

**US3372092**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'I'	System	03 Sep 2020 19:25:43

**US3372092**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	09 Sep 2020 18:14:04

**US3372092**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '9 Sep 2020'	(b) (4) Alexandra Arango (b) (4)	09 Sep 2020 18:14:04

US3372092

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	09 Sep 2020 18:14:04

US3372092

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Alexandra Arango (b) (4)	09 Sep 2020 18:14:04
	(b) (4)	



US3372092

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	09 Sep 2020 18:14:25

**US3372092**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'I'	System	09 Sep 2020 18:14:25

**US3372092**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	18 Sep 2020 13:03:04

**US3372092**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '18 Sep 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	18 Sep 2020 13:03:04

US3372092

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Clinic (Clinic)'	(b) (4) Kimarie Lee-Russell (b) (4)	18 Sep 2020 13:03:04

US3372092

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:37:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'VISIT2'	System	18 Sep 2020 13:03:04

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:52:58

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:52:58



US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '18 Sep 2020'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:52:58

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '09:10'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:52:58

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered '18 Sep 2020 09:10'	System	02 Oct 2020 15:52:58

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '36.6' C	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:52:58

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 15:52:58

**US3372092**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:52:58

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '62'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:52:58

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'bpm'	System	02 Oct 2020 15:52:58



US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:52:58

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'breaths/min'	System	02 Oct 2020 15:52:58

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '116'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:52:58

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'mmHg'	System	02 Oct 2020 15:52:58

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '72'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 15:52:58

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'mmHg'	System	02 Oct 2020 15:52:58

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:02:54

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:02:54



US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:02:54

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:02:54

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered empty.	System	02 Oct 2020 16:02:54

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:02:54

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:02:54

**US3372092**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:02:54

**US3372092**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:02:54

**US3372092**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered empty.	System	02 Oct 2020 16:02:54



US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:02:54

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered empty.	System	02 Oct 2020 16:02:54

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:02:54

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered empty.	System	02 Oct 2020 16:02:54

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:02:54

US3372092

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered empty.	System	02 Oct 2020 16:02:54

US3372092

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:03:15

**US3372092**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:49**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '18 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:03:15



US3372092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	18 Sep 2020 14:15:57

US3372092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User closed query 'Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:29:06
Query 'Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you.' answered with 'subject was asymptomatic and tested negative on second test' (Site from DM).	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:11:07
User opened query 'Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:41:28
User entered 'Confirmed COVID-19 (COVID)'	Kimarie Lee-Russell (b) (4)	18 Sep 2020 14:15:57

US3372092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	18 Sep 2020 14:15:57

US3372092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered empty.	System	18 Sep 2020 14:15:57

US3372092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	18 Sep 2020 14:15:57

US3372092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	18 Sep 2020 14:15:57

US3372092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered empty.	System	18 Sep 2020 14:15:57

US3372092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	18 Sep 2020 14:15:57



US3372092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered empty.	System	18 Sep 2020 14:15:57

US3372092

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered empty.	System	18 Sep 2020 14:15:57

US3372092

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:14:49

US3372092

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '18 Sep 2020'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:14:49

US3372092

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '09:38'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:14:49

US3372092

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered '18 Sep 2020 09:38'	System	02 Oct 2020 16:14:49

US3372092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:37:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '18 Sep 2020'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:29:19

**US3372092**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:29:19



US3372092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:37:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:29:19

**US3372092**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '09:35'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:29:19

**US3372092**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered '18 Sep 2020 09:35'	System	02 Oct 2020 16:29:19

US3372092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:37:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:29:23

US3372092

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:37:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:29:23

**US3372092**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:29:23

**US3372092**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered empty.	System	02 Oct 2020 16:29:23

US3372092

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	21 Sep 2020 18:45:12



US3372092

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'I'	System	21 Sep 2020 18:45:12

**US3372092**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 20:42:40

**US3372092**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:42:40

US3372092

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 20:42:40

US3372092

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:42:40

US3372092

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:17:13
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 13:15:40

**US3372092**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered '1'	System	14 Oct 2020 13:17:13
User entered empty.	System	14 Oct 2020 13:15:40

**US3372092**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 20:42:48



**US3372092**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:42:48

**US3372092**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:42:48

US3372092

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:42:48

**US3372092**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:18:17

**US3372092**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'I'	System	14 Oct 2020 13:18:17

**US3372092**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 20:42:52

**US3372092**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:42:52

**US3372092**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:42:52



**US3372092**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 20:42:52

**US3372092**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:18:38

**US3372092**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered '1'	System	14 Oct 2020 13:18:38

**US3372092**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:18:54

**US3372092**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:18:54

US3372092

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:18:54

**US3372092**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User entered 'VISIT3'	System	14 Oct 2020 13:18:54

US3372092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 20:43:08



US3372092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:43:08

**US3372092**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:43:08

US3372092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User entered empty.	System	15 Oct 2020 20:43:08

**US3372092**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 20:43:08

US3372092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:43:08

**US3372092**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:43:08

**US3372092**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:43:08

**US3372092**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User entered empty.	System	15 Oct 2020 20:43:08



US3372092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:43:08

US3372092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User entered empty.	System	15 Oct 2020 20:43:08

US3372092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 20:43:08

US3372092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User entered empty.	System	15 Oct 2020 20:43:08

US3372092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 20:43:08

US3372092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User entered empty.	System	15 Oct 2020 20:43:08

**US3372092**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06

US3372092

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06



**US3372092**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:49**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:43:18

US3372092

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:43:18

US3372092

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 20:43:46

US3372092

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '14 Oct 2020'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 20:43:46

US3372092

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '09:27'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 20:43:46

US3372092

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:03:06
User entered '14 Oct 2020 09:27'	System	15 Oct 2020 20:43:46

US3372092

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 20:43:53

**US3372092**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered '1'	System	15 Oct 2020 20:43:53



**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 64'	System	19 Aug 2020 13:48:05

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Have you been exposed to someone with 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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Please 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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

US3372092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

[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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28



**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28



**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Please 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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

US3372092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

[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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28



**US3372092**

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

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**Generated On: 11 Aug 2021 22:37:49**

[Please 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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

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

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**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28
Data entry locked.	System	19 Aug 2020 13:48:05
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 13:48:05

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28
Data entry locked.	System	19 Aug 2020 13:48:05
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 13:48:05

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 71'	System	19 Aug 2020 13:48:05

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Have you been exposed to someone with 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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

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**Generated On: 11 Aug 2021 22:37:49**

[Please 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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28



**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28



**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

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**Generated On: 11 Aug 2021 22:37:49**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

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**Generated On: 11 Aug 2021 22:37:49**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

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**Generated On: 11 Aug 2021 22:37:49**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28



**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Please 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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

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**Generated On: 11 Aug 2021 22:37:49**

[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)	24 Apr 2021 11:08:22
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28
Data entry locked.	System	19 Aug 2020 13:48:05
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 13:48:05

**US3372092**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28
Data entry locked.	System	19 Aug 2020 13:48:05
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 13:48:05



**US3372092**

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**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 78'	System	19 Aug 2020 13:48:05

**US3372092**

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

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[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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Have you been exposed to someone with 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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

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

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[Please 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)
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

US3372092

Folder: Safety Follow Up Diary (1)

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[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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

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**Generated On: 11 Aug 2021 22:37:49**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28



**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

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**Generated On: 11 Aug 2021 22:37:49**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

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**Generated On: 11 Aug 2021 22:37:49**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28



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**Generated On: 11 Aug 2021 22:37:49**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Please 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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28



**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Please 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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28
Data entry locked.	System	19 Aug 2020 13:48:05
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 13:48:05

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28
Data entry locked.	System	19 Aug 2020 13:48:05
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 13:48:05

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28
Data entry locked.	System	19 Aug 2020 13:48:05
User entered 'Day 92'	System	19 Aug 2020 13:48:05

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Have you been exposed to someone with 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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Please 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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28



US3372092

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

[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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28



**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Please 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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:37:49

[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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

**US3372092**

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

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**Generated On: 11 Aug 2021 22:37:49**

[Please 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)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28

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

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28
Data entry locked.	System	19 Aug 2020 13:48:05
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 13:48:05

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:17:28
Data entry locked.	System	19 Aug 2020 13:48:05
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 13:48:05



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 04:17:28

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 04:17:28



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 04:17:28

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:17:28



**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:17:28

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 04:17:28



**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 04:17:28



**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:17:28



**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 04:17:28



**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:17:28

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[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 (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-03-23T14:29:50-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '8c994bdb-9e76-4005-819d-cb41fb0c18f8' User entered 'No (N)'	System	23 Mar 2021 18:30:08
	System	23 Mar 2021 18:30:08

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Have you been exposed to someone with 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 (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-03-23T14:29:54-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '8c994bdb-9e76-4005-819d-cb41fb0c18f8'	System	23 Mar 2021 18:30:08
User entered 'No (N)'	System	23 Mar 2021 18:30:08

**US3372092**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-03-23T14:30:04-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '8c994bdb-9e76-4005-819d-cb41fb0c18f8' User entered '23 Mar 2021 14:30:04'	System	23 Mar 2021 18:30:08
	System	23 Mar 2021 18:30:08

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 04:17:28



**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[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 (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-03-30T14:51:28-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '118ea11e-4d38-4262-8a14-c13bc9199c69'	System	30 Mar 2021 18:51:44
User entered 'No (N)'	System	30 Mar 2021 18:51:44

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Have you been exposed to someone with 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 (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-03-30T14:51:34-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '118ea11e-4d38-4262-8a14-c13bc9199c69'	System	30 Mar 2021 18:51:44
User entered 'No (N)'	System	30 Mar 2021 18:51:44

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-03-30T14:51:40-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '118ea11e-4d38-4262-8a14-c13bc9199c69' User entered '30 Mar 2021 14:51:40'	System	30 Mar 2021 18:51:44
	System	30 Mar 2021 18:51:44

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:17:28



**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[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 (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-04-05T11:19:45-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'e9b10326-466c-41a6-8113-832dd2d9ac6a' User entered 'No (N)'	System	05 Apr 2021 15:19:58
	System	05 Apr 2021 15:19:58

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Have you been exposed to someone with 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 (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-04-05T11:19:48-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'e9b10326-466c-41a6-8113-832dd2d9ac6a' User entered 'No (N)'	System	05 Apr 2021 15:19:58

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-04-05T11:19:53-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'e9b10326-466c-41a6-8113-832dd2d9ac6a'	System	05 Apr 2021 15:19:58
User entered '05 Apr 2021 11:19:53'	System	05 Apr 2021 15:19:58

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[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 (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-04-09T08:58:02-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'a2593433-d958-49e5-acce-e9bfd8a0e55'	System	09 Apr 2021 12:58:15
User entered 'No (N)'	System	09 Apr 2021 12:58:15

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Have you been exposed to someone with 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 (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-04-09T08:58:08-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'a2593433-d958-49e5-acce-e9fbfd8a0e55'	System	09 Apr 2021 12:58:15
User entered 'No (N)'	System	09 Apr 2021 12:58:15



**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-04-09T08:58:13-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'a2593433-d958-49e5-acce-e9fbfd8a0e55'	System	09 Apr 2021 12:58:15
User entered '09 Apr 2021 08:58:13'	System	09 Apr 2021 12:58:15

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[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 (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-04-16T08:54:23-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'c7b57d8c-d7dc-445f-a14e-b8eb2b47530c'	System	16 Apr 2021 12:54:33
User entered 'No (N)'	System	16 Apr 2021 12:54:33

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

Have you been exposed to someone with 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 (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-04-16T08:54:27-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'c7b57d8c-d7dc-445f-a14e-b8eb2b47530c'	System	16 Apr 2021 12:54:33
User entered 'No (N)'	System	16 Apr 2021 12:54:33

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-04-16T08:54:30-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: 'c7b57d8c-d7dc-445f-a14e-b8eb2b47530c' User entered '16 Apr 2021 08:54:30'	System	16 Apr 2021 12:54:33
	System	16 Apr 2021 12:54:33

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 04:17:28



**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[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 (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-04-23T08:41:25-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '35554505-79fb-44be-9c08-e5a38099b3e8' User entered 'No (N)'	System	23 Apr 2021 12:41:37
	System	23 Apr 2021 12:41:37

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Have you been exposed to someone with 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 (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-04-23T08:41:29-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '35554505-79fb-44be-9c08-e5a38099b3e8' User entered 'No (N)'	System	23 Apr 2021 12:41:37
	System	23 Apr 2021 12:41:37

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-04-23T08:41:35-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '35554505-79fb-44be-9c08-e5a38099b3e8' User entered '23 Apr 2021 08:41:35'	System	23 Apr 2021 12:41:37
	System	23 Apr 2021 12:41:37

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 04:17:28



**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 04:17:28



**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:17:28



**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 04:17:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 04:17:28



**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 04:17:28



**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:17:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 04:17:28



**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 04:17:28



**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:17:28



**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 04:17:28



**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:17:28

**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 04:17:28



**US3372092**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:37:49**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:17:28
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 04:17:28

US3372092

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:37:49

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)	24 Apr 2021 11:08:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-03-23T14:30:42-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '3ce573c3-7254-4c58-80ad-0f7acfee248c'	System	23 Mar 2021 18:30:53
User entered 'No (N)'	System	23 Mar 2021 18:30:53

**US3372092**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:08:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25FEBA35-AAEC-48D6-9A3F-43A4E46A66A7)', Time: '2021-03-23T14:30:49-04:00', User OID: 'PatientReportedOutcome (US3372092)', ODM File OID: '3ce573c3-7254-4c58-80ad-0f7acfee248c' User entered '23 Mar 2021 14:30:49'	System	23 Mar 2021 18:30:53
	System	23 Mar 2021 18:30:53

**US3372092**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	13 Nov 2020 17:34:24

**US3372092**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '13 Nov 2020'	(b) (4) Danielle Theodore (b) (4)	13 Nov 2020 17:34:24
	(b) (4)	

**US3372092**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	13 Nov 2020 17:34:24

US3372092

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Danielle Theodore (b) (4)	13 Nov 2020 17:34:24
	(b) (4)	

US3372092

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	13 Nov 2020 17:34:31
	(b) (4)	



**US3372092**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:00:21
User entered 'I'	System	13 Nov 2020 17:34:31

**US3372092**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	17 Dec 2020 21:02:31
	(b) (4)	

**US3372092**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '17 Dec 2020'	(b) (4) Danielle Theodore (b) (4)	17 Dec 2020 21:02:31
	(b) (4)	

**US3372092**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	17 Dec 2020 21:02:31

**US3372092**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	17 Dec 2020 21:02:31

US3372092

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	17 Dec 2020 21:02:37

**US3372092**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User entered 'I'	System	17 Dec 2020 21:02:37

**US3372092**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	16 Jan 2021 17:37:33



**US3372092**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '16 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	16 Jan 2021 17:37:33
	(b) (4)	

**US3372092**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	16 Jan 2021 17:37:33

US3372092

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Danielle Theodore (b) (4)	16 Jan 2021 17:37:33
	(b) (4)	

**US3372092**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	16 Jan 2021 17:37:59

**US3372092**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User entered '1'	System	16 Jan 2021 17:37:59

**US3372092**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	13 Feb 2021 01:04:46
	(b) (4)	

**US3372092**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '12 Feb 2021'	(b) (4) Danielle Theodore (b) (4)	13 Feb 2021 01:04:46

**US3372092**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Feb 2021 01:04:46



US3372092

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:37:49

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Danielle Theodore (b) (4)	13 Feb 2021 01:04:46
	(b) (4)	

US3372092

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	13 Feb 2021 01:05:07
	(b) (4)	

**US3372092**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User entered 'I'	System	13 Feb 2021 01:05:07

**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:30:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:29:14

**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:30:40
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:29:14

US3372092

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:37:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:30:40
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:29:14

**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User entered 'VISIT4'	System	23 Mar 2021 21:29:14

US3372092

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User closed query 'Per CDM: Thank you for the response. However, since both visits occurred the same day, it is expected to have the same information recorded. Kindly review and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 04:10:53
Query 'Per CDM: Thank you for the response. However, since both visits occurred the same day, it is expected to have the same information recorded. Kindly review and update as needed, else provide clarification. ' answered with 'data correct as is ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 16:27:51
User opened query 'Per CDM: Thank you for the response. However, since both visits occurred the same day, it is expected to have the same information recorded. Kindly review and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 16:57:26
User closed query 'Per CDM re-query: Please update the data same as on OL-D57. or else clarify.Thank you' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 16:57:26
Query 'Per CDM re-query: Please update the data same as on OL-D57. or else clarify.Thank you' answered with 'The sponsor does not want duplicate data. Data correct as is.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 14:43:40
User opened query 'Per CDM re-query: Please update the data same as on OL-D57. or else clarify.Thank you' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:20:43
User closed query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" is recorded as "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:20:43



US3372092

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However,  "Vital signs" is recorded as "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' answered with 'data correct as is' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 21:35:00
User opened query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" is recorded as "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 02:51:18
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:07
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Apr 2021 21:44:54

US3372092

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:07
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Apr 2021 21:44:54

**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:07
User entered empty.	(b) (4) Peter Jacob (b) (4)	02 Apr 2021 21:44:54

**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered empty.	System	02 Apr 2021 21:44:54

US3372092

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:07
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Apr 2021 21:44:54

**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:07
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Apr 2021 21:44:54

**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:07
User entered empty.	(b) (4) Peter Jacob (b) (4)	02 Apr 2021 21:44:54

**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:07
User entered empty.	(b) (4) Peter Jacob (b) (4)	02 Apr 2021 21:44:54



**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered empty.	System	02 Apr 2021 21:44:54

US3372092

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:07
User entered empty.	(b) (4) Peter Jacob (b) (4)	02 Apr 2021 21:44:54

US3372092

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered empty.	System	02 Apr 2021 21:44:54

**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:07
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Apr 2021 21:44:54

**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered empty.	System	02 Apr 2021 21:44:54

**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 13:16:07
User entered empty.	(b) (4) Peter Jacob (b) (4)	02 Apr 2021 21:44:54

US3372092

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01
User entered empty.	System	02 Apr 2021 21:44:54

US3372092

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01



US3372092

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:30:01

**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:49**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:30:03

**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:49**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:32:21
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:30:03

US3372092

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:44:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:31:35

US3372092

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:44:44
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:31:35

US3372092

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:44:44
User entered '14:40'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:31:35

US3372092

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User entered '23 Mar 2021 14:40'	System	23 Mar 2021 21:31:35

US3372092

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:44:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:31:40



**US3372092**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:42:30
User entered 'I'	System	23 Mar 2021 21:31:40

**US3372092**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:18:45
	(b) (4)	
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	16 Apr 2021 17:28:10
	(b) (4)	

**US3372092**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:18:45
	(b) (4)	
User entered '16 Apr 2021'	Danielle Theodore (b) (4)	16 Apr 2021 17:28:10
	(b) (4)	

**US3372092**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:18:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	16 Apr 2021 17:28:10
	(b) (4)	

**US3372092**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:18:45
	(b) (4)	
User entered empty.	Danielle Theodore (b) (4)	16 Apr 2021 17:28:10
	(b) (4)	

US3372092

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Apr 2021 19:18:45
	(b) (4)	
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	16 Apr 2021 17:28:16
	(b) (4)	

**US3372092**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 17:28:16

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:37:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:06:10



**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:06:10

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:06:10

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 17:06:10

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:37:49**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:06:25

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:37:49**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:43
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 21:11:30
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:16:38

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:37:49

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:06:25

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:37:49**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:43
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 21:11:30
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:16:38

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:37:49

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:06:25



US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:37:49

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Placebo (Placebo)' reason for change:	(b) (4)	
Data Entry Error	Danielle Theodore (b) (4)	02 Feb 2021 15:00:16
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	27 Jan 2021 17:06:25

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:37:49

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Placebo (Placebo)' reason for change:	(b) (4)	
Data Entry Error	Danielle Theodore (b) (4)	02 Feb 2021 15:00:16
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	27 Jan 2021 17:06:25

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:37:49

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Placebo (Placebo)' reason for change:	(b) (4)	
Data Entry Error	Danielle Theodore (b) (4)	02 Feb 2021 15:00:16
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	27 Jan 2021 17:06:25

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:37:49**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Danielle Theodore (b) (4)	02 Feb 2021 15:00:16
User entered 'No (N)'	(b) (4), (b) (6)	27 Jan 2021 17:06:25

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:37:49**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered '1'	System	02 Feb 2021 15:00:16
User entered empty.	System	27 Jan 2021 17:06:25

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'I'	System	02 Feb 2021 15:00:16
User entered empty.	System	27 Jan 2021 17:06:25

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered empty.	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered empty.	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38
	(b) (4)	



US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered empty.	System	10 Mar 2021 20:30:38
DataPoint set to visible.	System	02 Feb 2021 15:00:16

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered empty.	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered empty.	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered empty.	System	10 Mar 2021 20:30:38
DataPoint set to visible.	System	02 Feb 2021 15:00:16

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User accepted default value 'Pre-Dose (PREDOSE)'	Danielle Theodore (b) (4)	10 Mar 2021 20:30:38
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered '26 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	15 Mar 2021 21:16:46
User entered '14:30' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	15 Mar 2021 21:16:46
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	15 Mar 2021 21:12:33
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	15 Mar 2021 21:12:33
User entered '15:03' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 21:12:33
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	10 Mar 2021 20:34:41
User entered '14:30'	Danielle Theodore (b) (4) (b) (4)	10 Mar 2021 20:30:38



**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered '26 Jan 2021 14:30'	System	15 Mar 2021 21:16:46
User entered '26 Jan 2021 15:03'	System	15 Mar 2021 21:12:33
User entered '26 Jan 2021 14:30'	System	10 Mar 2021 20:30:38

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered '98.0' F	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered 'Other (Other)'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38
	(b) (4)	

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered 'forehead'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered '69'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'bpm'	System	10 Mar 2021 20:30:38

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered '17'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'breaths/min'	System	10 Mar 2021 20:30:38



US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered '127'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'mmHg'	System	10 Mar 2021 20:30:38

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered '77'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'mmHg'	System	10 Mar 2021 20:30:38

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered empty.	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered empty.	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:30:38
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:37:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered empty.	System	10 Mar 2021 20:30:38
DataPoint set to visible.	System	02 Feb 2021 15:00:16

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User accepted default value 'Post-Dose (POSTDOSE)'	Danielle Theodore (b) (4)	10 Mar 2021 20:31:48
	(b) (4)	



US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:31:48
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered '26 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:31:48
	(b) (4)	

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered '16:35'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:31:48
	(b) (4)	

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered '26 Jan 2021 16:35'	System	10 Mar 2021 20:31:48

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered '97.9' F	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:31:48

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered 'Other (Other)'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:31:48
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered 'forehead'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:31:48
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered '65'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:31:48
	(b) (4)	



**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'bpm'	System	10 Mar 2021 20:31:48

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered '18'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:31:48
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'breaths/min'	System	10 Mar 2021 20:31:48

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered '124'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:31:48
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'mmHg'	System	10 Mar 2021 20:31:48

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered '74'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:31:48
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'mmHg'	System	10 Mar 2021 20:31:48

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:43
User entered 'No (N)'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:32:15



US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:43
User entered empty.	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:32:15
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:43
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:34:20

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:43
User entered empty.	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:34:20
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

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)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:43
User entered empty.	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:34:20
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'mRNA-1273'	System	10 Mar 2021 20:34:20
DataPoint set to visible.	System	02 Feb 2021 15:00:16

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:43
User entered '26 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:34:20
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:43
User entered '15:03' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Mar 2021 21:13:33
User entered '14:05' reason for change: Data Entry Error	Danielle Theodore (b) (4) (b) (4)	10 Mar 2021 20:34:41
User entered '15:03'	Danielle Theodore (b) (4) (b) (4)	10 Mar 2021 20:34:20

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered '26 Jan 2021 15:03'	System	15 Mar 2021 21:13:33
User entered '26 Jan 2021 14:05'	System	10 Mar 2021 20:34:41
User entered '26 Jan 2021 15:03'	System	10 Mar 2021 20:34:20



US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:27:43
User entered 'Left Arm (LEFT ARM)'	(b) (4) Danielle Theodore (b) (4)	10 Mar 2021 20:34:20
	(b) (4)	

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'ONCE'	System	10 Mar 2021 20:34:20

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'INTRAMUSCULAR'	System	10 Mar 2021 20:34:20

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:49**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:06:54

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:49**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:06:54

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:49**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '14:05'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:06:54

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:49**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered '26 Jan 2021 14:05'	System	27 Jan 2021 17:06:54

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:37:49**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:07:08



**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:37:49**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:07:08

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:37:49**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '14:03'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:07:08

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:37:49**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered '26 Jan 2021 14:03'	System	27 Jan 2021 17:07:08

US3372092

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	02 Feb 2021 15:00:24
	(b) (4)	

**US3372092**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'I'	System	02 Feb 2021 15:00:24

**US3372092**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	02 Feb 2021 15:00:39

**US3372092**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '2 Feb 2021'	(b) (4) Danielle Theodore (b) (4)	02 Feb 2021 15:00:39

**US3372092**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	02 Feb 2021 15:00:39
	(b) (4)	



**US3372092**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	02 Feb 2021 15:00:39

**US3372092**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	02 Feb 2021 15:00:45
	(b) (4)	

**US3372092**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'I'	System	02 Feb 2021 15:00:45

**US3372092**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered '1'	System	02 Feb 2021 15:00:45
DataPoint set to visible.	System	02 Feb 2021 15:00:45

**US3372092**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:18

**US3372092**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:18

US3372092

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:37:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:18

**US3372092**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered 'OLD29'	System	24 Feb 2021 14:55:18



US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Feb 2021 14:57:00

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '14:31'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered '23 Feb 2021 14:31'	System	24 Feb 2021 14:57:00

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00



**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '67'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered 'bpm'	System	24 Feb 2021 14:57:00

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '16'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered 'breaths/min'	System	24 Feb 2021 14:57:00

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:37:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '118'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered 'mmHg'	System	24 Feb 2021 14:57:00

**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '70'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered 'mmHg'	System	24 Feb 2021 14:57:00



**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Feb 2021 14:57:00

**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '15:28'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered '23 Feb 2021 15:28'	System	24 Feb 2021 14:57:00

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00



**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '69'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered 'bpm'	System	24 Feb 2021 14:57:00

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '15'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered 'breaths/min'	System	24 Feb 2021 14:57:00

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '118'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

**US3372092**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered 'mmHg'	System	24 Feb 2021 14:57:00

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '70'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:00

US3372092

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:37:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered 'mmHg'	System	24 Feb 2021 14:57:00



US3372092

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:37:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:06

**US3372092**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:49**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:06

**US3372092**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:49**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:18

**US3372092**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:49**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:18

US3372092

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

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)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:18

US3372092

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered 'mRNA-1273'	System	24 Feb 2021 14:57:18
DataPoint set to visible.	System	02 Feb 2021 15:00:45

US3372092

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:18

**US3372092**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:49**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered '14:58'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:18



**US3372092**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:49**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered '23 Feb 2021 14:58'	System	24 Feb 2021 14:57:18

US3372092

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:18

US3372092

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:37:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered 'ONCE'	System	24 Feb 2021 14:57:18

**US3372092**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:37:49**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 14:57:18

US3372092

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:37:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 15:14:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:57:22

**US3372092**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:01
User entered 'I'	System	24 Feb 2021 14:57:22

**US3372092**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	02 Mar 2021 15:43:56
	(b) (4)	

**US3372092**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered '2 Mar 2021'	(b) (4) Danielle Theodore (b) (4)	02 Mar 2021 15:43:56
	(b) (4)	



**US3372092**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	02 Mar 2021 15:43:56
	(b) (4)	

**US3372092**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:37:49**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered empty.	(b) (4) Danielle Theodore (b) (4)	02 Mar 2021 15:43:56
	(b) (4)	

**US3372092**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:28:21
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	02 Mar 2021 15:44:02
	(b) (4)	

**US3372092**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:37:49**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'I'	System	02 Mar 2021 15:44:02

**US3372092**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:25

**US3372092**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:25

**US3372092**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:25

**US3372092**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:37:49**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'OLD57'	System	23 Mar 2021 21:32:25



**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:55

**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:55

**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered '14:21'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:55

**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered '23 Mar 2021 14:21'	System	23 Mar 2021 21:32:55

**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:55

**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:55

**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered 'forehead'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:55

**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered '70'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:55



**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'bpm'	System	23 Mar 2021 21:32:55

**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered '16'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:55

US3372092

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:37:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'breaths/min'	System	23 Mar 2021 21:32:55

**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered '134'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:55

**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'mmHg'	System	23 Mar 2021 21:32:55

**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered '82'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:32:55

**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered 'mmHg'	System	23 Mar 2021 21:32:55

**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11



**US3372092**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:37:49**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11

**US3372092**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:49**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:33:03

**US3372092**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:37:49**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:33:03

**US3372092**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:49**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:33:27

US3372092

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:37:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:33:27

**US3372092**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:49**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User signature succeeded.	Mira Baron (b) (4)	23 Mar 2021 21:48:13
User entered '14:40'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:33:27

**US3372092**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:37:49**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:11
User entered '23 Mar 2021 14:40'	System	23 Mar 2021 21:33:27

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 22:37:49**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:43:43
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:57:15



US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 21:07:23
User entered		
'USA-US056-2021-mRNA-1273-P301000011'	System	18 Mar 2021 21:07:17
User entered 'New'	(b) (4), (b) (6)	18 Mar 2021 21:07:17

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Feb 2021 20:00:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 20:00:54
Data point term sent to Coder	System	18 Feb 2021 19:59:43
User entered 'Covid-19'	(b) (4), (b) (6)	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Mar 2021 15:58:07
User closed query 'Per DM CLR - RQ: Site's response noted. However, please review the list of Solicited Adverse Reaction per protocol section 8.3.4 and determine if "COVID-19" is included in the list. Review if this is an Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:42:45
Query 'Per DM CLR - RQ: Site's response noted. However, please review the list of Solicited Adverse Reaction per protocol section 8.3.4 and determine if "COVID-19" is included in the list. Review if this is an Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 16:06:28
Signature has been broken.	(b) (4), (b) (6)	23 Mar 2021 15:31:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 15:31:52
User opened query 'Per DM CLR - RQ: Site's response noted. However, please review the list of Solicited Adverse Reaction per protocol section 8.3.4 and determine if "COVID-19" is included in the list. Review if this is an Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 07:38:13
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this is not one of the solicited adverse reaction per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 00:44:48
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this is not one of the solicited adverse reaction per protocol. Review and update entry as appropriate.' answered with 'Data correct as is.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 17:10:06

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this is not one of the solicited adverse reaction per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 14:02:51
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Feb 2021 19:58:44

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered '10:14'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44



**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 10:14'	System	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered '10:14'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 10:14'	System	18 Feb 2021 19:58:44

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44



US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44



US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Feb 2021 07:42:18
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'data correct as stated in the Source' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 20:01:48
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	18 Feb 2021 19:58:44
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered '1'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44



US3372092

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:37:49

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	18 Feb 2021 20:14:44
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Feb 2021 19:58:44

**US3372092**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Feb 2021 19:58:44

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:37:49

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:43:43
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	Peter Jacob (b) (4)	02 Oct 2020 16:34:26

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:37:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
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)	02 Oct 2020 16:40:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 16:40:53
Data point term sent to Coder	System	02 Oct 2020 16:40:05
User entered 'atorvastatin'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:39:49

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:39:49

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'hypercholesterolemia'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:39:49



**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '20'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:39:49

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:39:49

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:37:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:39:49
	(b) (4)	

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:39:49

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:37:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:39:49
	(b) (4)	

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:39:49

US3372092

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:49**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:39:49
	(b) (4)	

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:37:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered 'un UNK 2010'	Peter Jacob (b) (4)	02 Oct 2020 16:39:49
	(b) (4)	



**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:39:49

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:39:49

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:37:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:39:49
	(b) (4)	

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:37:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:39:49

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 16:39:49

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 16:39:49

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 16:39:49

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:37:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Oct 2020 16:43:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 16:43:49
Data point term sent to Coder	System	02 Oct 2020 16:43:09
User entered 'metoprolol'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:42:40



**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:42:40

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'hypertension'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:42:40

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:37:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '50'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:42:40

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:37:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	02 Oct 2020 16:42:40
	(b) (4)	

US3372092

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:37:49**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:42:40
	(b) (4)	

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:37:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:42:40

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:37:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:42:40
	(b) (4)	

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:42:40



US3372092

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:37:49**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:42:40
	(b) (4)	

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:37:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered 'un Jan 2020'	Peter Jacob (b) (4)	02 Oct 2020 16:42:40
	(b) (4)	

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:37:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:42:40

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	02 Oct 2020 16:42:40
	(b) (4)	

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:37:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:42:40
	(b) (4)	

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:42:40

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 16:42:40

US3372092

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 16:42:40



**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 16:42:40

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:37:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Oct 2020 16:52:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 16:52:48
Data point term sent to Coder User entered 'lisinopril'	System Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:51:25 02 Oct 2020 16:51:12

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:37:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:51:12

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:37:49**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'hypertension'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:51:12

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:37:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '10'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:51:12

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:37:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:51:12

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:37:49**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:51:12

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:37:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:51:12



US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:37:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:51:12

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:37:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:51:12

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:37:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:51:12

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:37:49**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'un UNK 2005'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:51:12

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:37:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:51:12

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:37:49**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:51:12

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:37:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'un UNK 2005'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:51:12

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:37:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:51:12



**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:37:49**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User entered '1'	System	02 Oct 2020 16:51:12

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User entered '1'	System	02 Oct 2020 16:51:12

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:36
User entered '804 (804)'	System	02 Oct 2020 16:51:12

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:37:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 16:56:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 16:56:49
Data point term sent to Coder	System	02 Oct 2020 16:55:30
User entered 'vitamin D3'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:54:46

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:37:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User closed query 'Per CDM: Please consider checking yes for "Prophylaxis", as the indication is "DIETARY SUPPLEMENT", or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:16:04
Query 'Per CDM: Please consider checking yes for "Prophylaxis", as the indication is "DIETARY SUPPLEMENT", or clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 17:33:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:33:32
User opened query 'Per CDM: Please consider checking yes for "Prophylaxis", as the indication is "DIETARY SUPPLEMENT", or clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 17:26:28
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:35:10
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' answered with 'Correct as entered' (Site from DM).	Mary Sergalis (b) (4)	13 Nov 2020 20:04:44
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:46:47
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:54:46

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:54:46

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '5000'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:54:46

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'IU (IU)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:54:46



US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:37:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:54:46
	(b) (4)	

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:54:46

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:37:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:54:46
	(b) (4)	

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:54:46

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:37:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:54:46
	(b) (4)	

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered 'un Aug 2018'	Peter Jacob (b) (4)	02 Oct 2020 16:54:46
	(b) (4)	

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	02 Oct 2020 16:54:46
	(b) (4)	

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	02 Oct 2020 16:54:46
	(b) (4)	



**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:37:49**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:54:46
	(b) (4)	

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:54:46

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 16:54:46

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 16:54:46

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 16:54:46

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:37:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COENZYME Q10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Oct 2020 16:59:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 16:59:54
Data point term sent to Coder	System	02 Oct 2020 16:58:33
User entered 'coenzyme Q10'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:57:34

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:37:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User closed query 'Per CDM: Please consider checking yes for "Prophylaxis", as the indication is "DIETARY SUPPLEMENT", or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:16:13
Query 'Per CDM: Please consider checking yes for "Prophylaxis", as the indication is "DIETARY SUPPLEMENT", or clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 17:33:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:33:50
User opened query 'Per CDM: Please consider checking yes for "Prophylaxis", as the indication is "DIETARY SUPPLEMENT", or clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 17:29:40
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:35:23
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' answered with 'Correct as entered' (Site from DM).	Mary Sergalis (b) (4)	13 Nov 2020 20:04:54
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:47:19
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:57:34

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:37:49**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:57:34



US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:37:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '100'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:57:34
	(b) (4)	

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:37:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	02 Oct 2020 16:57:34
	(b) (4)	

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:37:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:57:34
	(b) (4)	

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:37:49**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:57:34
	(b) (4)	

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:37:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:57:34
	(b) (4)	

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:37:49**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:57:34

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:37:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:57:34
	(b) (4)	

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:37:49

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'un UNK 2017'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:57:34



US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:37:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:57:34

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:37:49**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:57:34

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:37:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 16:57:34
	(b) (4)	

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:37:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:57:34

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:37:49**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 16:57:34

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 16:57:34

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 16:57:34

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:37:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 16:59:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 16:59:55
Data point term sent to Coder	System	02 Oct 2020 16:59:38
User entered 'influenza vaccine'	Peter Jacob (b) (4)	02 Oct 2020 16:59:14



US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:37:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:59:14

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:37:49**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'influenza prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:59:14

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:37:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0.5'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:59:14

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:37:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:59:14

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:37:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:59:14

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:37:49**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:59:14

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:37:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:59:14

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:37:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 16:59:14



US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:37:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:59:14

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:37:49

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'un Oct 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:59:14

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:37:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:59:14

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:37:49**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:59:14

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:37:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'un Oct 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:59:14

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:37:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:59:14

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:37:49**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User entered empty.	System	02 Oct 2020 16:59:14

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User entered empty.	System	02 Oct 2020 16:59:14



**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:41
User entered empty.	System	02 Oct 2020 16:59:14

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:37:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 17:04:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 17:04:50
Data point term sent to Coder	System	02 Oct 2020 17:03:44
User entered 'shingrix'	Peter Jacob (b) (4)	02 Oct 2020 17:02:44

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:37:49**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 17:02:44

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:37:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'herpes zoster prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 17:02:44

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:37:49**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0.5'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:02:44

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:37:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 17:02:44

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:37:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:02:44

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:37:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:02:44



US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:37:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:02:44

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:37:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 17:02:44

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:37:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:02:44

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:37:49**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '10 Jul 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:02:44

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:37:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:02:44

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:37:49**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:02:44

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:37:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '10 Jul 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:02:44

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:37:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 17:02:44



**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:37:49**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User entered empty.	System	02 Oct 2020 17:02:44

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User entered empty.	System	02 Oct 2020 17:02:44

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:45
User entered empty.	System	02 Oct 2020 17:02:44

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:37:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Oct 2020 17:05:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 17:05:52
Data point term sent to Coder	System	02 Oct 2020 17:04:47
User entered 'pneumococcal vaccine'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:04:16

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:37:49**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:04:16

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:37:49**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'pneumonia prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:04:16

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:37:49**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0.5'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 17:04:16

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:37:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:04:16



US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:37:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:04:16

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:37:49**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 17:04:16

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:37:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:04:16

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:37:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 17:04:16

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:37:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:04:16

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:37:49**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '09 Aug 2017'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:04:16

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:37:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:04:16

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:37:49**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:04:16



US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:37:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '09 Aug 2017'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:04:16

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:37:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:04:16

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:37:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User entered empty.	System	02 Oct 2020 17:04:16

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:37:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User entered empty.	System	02 Oct 2020 17:04:16

US3372092

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:50
User entered empty.	System	02 Oct 2020 17:04:16

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:37:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: TETANUS VACCINES, PRODUCT: TETANUS VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Oct 2020 04:27:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:27:48
Data point term sent to Coder	System	02 Oct 2020 17:15:05
User entered 'tetanus vaccine'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:14:28

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:37:49**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 17:14:28

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:37:49**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'infection prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:14:28



US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:37:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0.5'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:14:28

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:37:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 17:14:28

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:37:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:14:28

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:37:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:14:28

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:37:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:14:28

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:37:49**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 17:14:28

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:37:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:14:28

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:37:49**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '20 Sep 2011'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:14:28



US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:37:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:14:28

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:37:49**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:14:28

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:37:49**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '20 Sep 2011'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:14:28

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:37:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 17:14:28

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:37:49**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User entered empty.	System	02 Oct 2020 17:14:28

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User entered empty.	System	02 Oct 2020 17:14:28

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:57:55
User entered empty.	System	02 Oct 2020 17:14:28

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:37:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 18:53:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 18:53:47
Data point term sent to Coder	System	13 Nov 2020 18:37:33
User entered 'Influenza vaccine'	Elena Acosta (b) (4)	13 Nov 2020 18:37:06



US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:37:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Yes (Y)'	(b) (4) Elena Acosta (b) (4)	13 Nov 2020 18:37:06

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:37:49**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Influenza Prevention'	(b) (4) Elena Acosta (b) (4) (b) (4)	13 Nov 2020 18:37:06

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:37:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0.5'	(b) (4) Elena Acosta (b) (4)	13 Nov 2020 18:37:06

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:37:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'mL (mL)'	(b) (4) Elena Acosta (b) (4)	13 Nov 2020 18:37:06

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:37:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Elena Acosta (b) (4)	13 Nov 2020 18:37:06

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:37:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'once (ONCE)'	(b) (4) Elena Acosta (b) (4) (b) (4)	13 Nov 2020 18:37:06

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:37:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Elena Acosta (b) (4)	13 Nov 2020 18:37:06

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:37:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Elena Acosta (b) (4)	13 Nov 2020 18:37:06



US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:37:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered empty.	(b) (4) Elena Acosta (b) (4)	13 Nov 2020 18:37:06

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:37:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '30 Oct 2020'	(b) (4) Elena Acosta (b) (4)	13 Nov 2020 18:37:06

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:37:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '0'	(b) (4) Elena Acosta (b) (4)	13 Nov 2020 18:37:06

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:37:49**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Elena Acosta (b) (4)	13 Nov 2020 18:37:06

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:37:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered '30 Oct 2020'	(b) (4) Elena Acosta (b) (4)	13 Nov 2020 18:37:06

US3372092

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:37:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Elena Acosta (b) (4)	13 Nov 2020 18:37:06

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:37:49**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User entered empty.	System	13 Nov 2020 18:37:06

**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User entered empty.	System	13 Nov 2020 18:37:06



**US3372092**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:37:49**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:58:00
User entered empty.	System	13 Nov 2020 18:37:06

US3372092

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:37:49**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 17:34:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 16:33:00

**US3372092**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 22:37:49**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:09:08
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:49:48
User entered '18 Sep 2020'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 20:45:08

US3372092

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:37:49

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:09:08
User closed query 'Per CDM re-query: Thank you for your answer. However, there is still no "Covid-19 assessments" done. Please be aware that according to a protocol, Covid-19 assessments folder and illness visit should be completed. Thank you!' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 12:39:00
Query 'Per CDM re-query: Thank you for your answer. However, there is still no "Covid-19 assessments" done. Please be aware that according to a protocol, Covid-19 assessments folder and illness visit should be completed. Thank you!' answered with 'According to the Source there is no information within Covid Assessment or Illness visit for this Subject.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 15:57:50
User opened query 'Per CDM re-query: Thank you for your answer. However, there is still no "Covid-19 assessments" done. Please be aware that according to a protocol, Covid-19 assessments folder and illness visit should be completed. Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:19:08
User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'Covid -19 Assessment' form ,`Adverse event' form and 'End of Study / Study Discontinuation'form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:19:08
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:49:48
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'Covid -19 Assessment' form ,`Adverse event' form and 'End of Study / Study Discontinuation'form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' answered with 'procol deviation will be filed' (Site from DM).	Peter Jacob (b) (4)	22 Feb 2021 19:27:50

US3372092

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:37:49

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'Covid -19 Assessment' form ,`Adverse event' form and 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:24:12
User entered 'Due to SARS-COV-2 (COVID)'	Peter Jacob (b) (4) (b) (4)	15 Oct 2020 20:45:08

US3372092

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:37:49

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:09:08
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:49:48
User entered empty.	Peter Jacob (b) (4)	15 Oct 2020 20:45:08

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'USA-US056-2021-MRNA-1273-P301000011'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17



**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'Mira'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'Baron'	(b) (4) System	18 Mar 2021 21:07:17



**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered '2277 Palm beach Lakes Blvd'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'West Palm Beach'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered '33409'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'US'	(b) (4) System	18 Mar 2021 21:07:42

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Mar 2021 14:52:39
User entered '1'	System	18 Mar 2021 21:07:42

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'USA-US056-2021-MRNA-1273-P301000011'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17



**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'Mira'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'Baron'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered '2277 Palm beach Lakes Blvd'	(b) (4) System	18 Mar 2021 21:07:17



**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'West Palm Beach'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered '33409'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'US'	(b) (4) System	18 Mar 2021 21:07:42

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Mar 2021 14:52:39
User entered '1'	System	18 Mar 2021 21:07:42

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 22:37:49**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered '18/Mar/2021 17:07'	(b) (4) System	18 Mar 2021 21:07:42

US3372092

Folder: SAE USA-US056-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:37:49

**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)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:07:42

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'USA-US056-2021-MRNA-1273-P301000011'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Serious](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17



**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'No (N)'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'Mira'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'Baron'	(b) (4) System	18 Mar 2021 21:07:17



**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered '2277 Palm beach Lakes Blvd'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'West Palm Beach'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered '33409'	(b) (4) System	18 Mar 2021 21:07:17

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:52:27
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:29:37
User entered 'US'	(b) (4) System	18 Mar 2021 21:07:42

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:37:49**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Mar 2021 14:52:39
User entered '1'	System	18 Mar 2021 21:07:42

**US3372092**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000011**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 22:37:49**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Mar 2021 15:58:07
User entered '24/Mar/2021 10:52'	(b) (4) System	24 Mar 2021 14:52:39

US3372092

Folder: SAE USA-US056-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:37:49

**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.	Mira Baron (b) (4)	24 Mar 2021 15:58:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:52:39