

US3372348 (Prod: Palm Beach Research Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:17:58

All time stamps listed in this document are displayed in GMT

US3372348

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 19:50:36

Generated On: 09 Jun 2021 17:17:58

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[Participant ID](#)

US3372348

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

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US3372348

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:20:41

Generated On: 09 Jun 2021 17:17:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3372348

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 23:15:25

Generated On: 09 Jun 2021 17:17:58

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
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) 16 Feb 2021 23:33:22

Generated On: 09 Jun 2021 17:17:58

Date of Informed Consent ( <i>dd MMM yyyy</i> )	7 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3372348

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 00:26:38

Generated On: 09 Jun 2021 17:17:58

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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) 17 Feb 2021 00:58:34

Generated On: 09 Jun 2021 17:17:58

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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) 17 Feb 2021 00:42:32

Generated On: 09 Jun 2021 17:17:58

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 00:42:32

Generated On: 09 Jun 2021 17:17:58

Condition	CORONARY ARTERY BYPASS GRAFT
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

US3372348

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 00:42:32

Generated On: 09 Jun 2021 17:17:58

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3372348

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 00:42:32

Generated On: 09 Jun 2021 17:17:58

Condition	CHRONIC LOWER BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3372348

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 00:42:32

Generated On: 09 Jun 2021 17:17:58

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 00:42:32

Generated On: 09 Jun 2021 17:17:58

Condition	PARTIAL LEFT BICEPS TENDON RUPTURE
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 03:36:49

Generated On: 09 Jun 2021 17:17:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	07 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	09:44 (24 HR)
Vital Signs Date and Time (derived)	07 SEP 2020 09:44
Height ( <i>xxx.x</i> )	176 cm
Weight ( <i>xxx.x</i> )	88.9 kg
BMI ( <i>xxx.x</i> )	28.69964 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	37 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	74 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:14:20

Generated On: 09 Jun 2021 17:17:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:24:41

Generated On: 09 Jun 2021 17:17:58

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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**

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

**No Risk Identified** False

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



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:24:41

Generated On: 09 Jun 2021 17:17:58

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:20:41

Generated On: 09 Jun 2021 17:17:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 27 Apr 2021 01:41:48

Generated On: 09 Jun 2021 17:17:58

What was the date of randomization? (dd MMM yyyy) 15 SEP 2020

What was the participant's randomization number? 113912

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 03:53:01

Generated On: 09 Jun 2021 17:17:58

Height	176 cm
Weight	88.1 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 03:53:01

Generated On: 09 Jun 2021 17:17:58

Height	176 cm
Weight	88.1 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)	15 SEP 2020
Time of assessment (00:00-23:59)	09:23 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 09:23
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	101 mmHg
Diastolic Blood Pressure units	MMHG

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:53:01

Generated On: 09 Jun 2021 17:17:58

Height	176 cm
Weight	88.1 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)	15 SEP 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 11:00
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	175 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	103 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:14:20

Generated On: 09 Jun 2021 17:17:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:50:53

Generated On: 09 Jun 2021 17:17:58

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) 15 SEP 2020

What was the treatment time? (00:00-23:59) 10:25 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 10:25

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



US3372348

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 00:10:26

Generated On: 09 Jun 2021 17:17:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 SEP 2020

Collection time (00:00-23:59)

09:43 (24 HR)

Collection date and time (derived)

15 SEP 2020 09:43

US3372348

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:27:24

Generated On: 09 Jun 2021 17:17:58

Collection date (dd MMM yyyy)			15 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:42	15 SEP 2020 09:42
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:45:05

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**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

97.9 °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

15 SEP 2020 10:58

PC Open Date & Time

15 SEP 2020 10:45

PC Close Date & Time

15 SEP 2020 13:15

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**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

97.7 °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	16 SEP 2020 07:50
PC Open Date & Time	15 SEP 2020 14:10
PC Close Date & Time	16 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 13:41

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**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

97.7 °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

17 SEP 2020 19:36

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 17:20

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59



US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 14:42

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**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

97.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

20 SEP 2020 19:14

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:17:58

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.8 °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

21 SEP 2020 12:01

---

PC Open Date & Time

21 SEP 2020 12:00

---

PC Close Date & Time

22 SEP 2020 11:59

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US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**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

15 SEP 2020 10:56

PC Open Date & Time

15 SEP 2020 10:45

PC Close Date & Time

15 SEP 2020 13:15

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 07:51

PC Open Date & Time

15 SEP 2020 14:10

PC Close Date & Time

16 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**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

16 SEP 2020 13:42

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**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

17 SEP 2020 19:37

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**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

18 SEP 2020 17:21

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59



US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**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

19 SEP 2020 14:43

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**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

20 SEP 2020 19:14

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 12:02

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**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 ☐

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 10:55
PC Open Date & Time	15 SEP 2020 10:45
PC Close Date & Time	15 SEP 2020 13:15

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**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 ☐

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 07:52
PC Open Date & Time	15 SEP 2020 14:10
PC Close Date & Time	16 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**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 ☒



US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 13:43
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**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 ☒

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 19:38
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 17:22
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

53 of 1981

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:17:58

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 14:43
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:17:58

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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US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:17:58

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 19:15
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:17:58

**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 ☒

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:17:58

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 12:03
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3372348

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:42:35

Generated On: 09 Jun 2021 17:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372348

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:45:05

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:42:35

Generated On: 09 Jun 2021 17:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372348

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:45:05

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:42:35

Generated On: 09 Jun 2021 17:17:58

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 OCT 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3372348

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:45:05

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:28:09

Generated On: 09 Jun 2021 17:17:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 20:28:10

Generated On: 09 Jun 2021 17:17:58

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)	13 OCT 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 09:10
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:28:10

Generated On: 09 Jun 2021 17:17:58

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	10:46 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 10:46
Temperature (xxx.x)	36 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3372348

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:28:09

Generated On: 09 Jun 2021 17:17:58

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.*

US3372348

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:28:09

Generated On: 09 Jun 2021 17:17:58

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) 13 OCT 2020

What was the treatment time? (00:00-23:59) 10:12 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 10:12

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

US3372348

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:28:09

Generated On: 09 Jun 2021 17:17:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

09:40 (24 HR)

Collection date and time (derived)

13 OCT 2020 09:40

US3372348

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:27:24

Generated On: 09 Jun 2021 17:17:58

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:38	13 OCT 2020 09:38
Nasopharyngeal Swab 2	No		



US3372348

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:28:09

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 11:05

PC Open Date & Time

13 OCT 2020 10:32

PC Close Date & Time

13 OCT 2020 13:02

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**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 97.7 °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	14 OCT 2020 06:31
PC Open Date & Time	13 OCT 2020 13:57
PC Close Date & Time	14 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**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 15 OCT 2020 08:01

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**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

97.7 °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

16 OCT 2020 08:35

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 06:24

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 07:36

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:17:58

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 08:13

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59



US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:17:58

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 07:04

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**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

13 OCT 2020 11:06

PC Open Date & Time

13 OCT 2020 10:32

PC Close Date & Time

13 OCT 2020 13:02

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**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

14 OCT 2020 06:31

PC Open Date & Time

13 OCT 2020 13:57

PC Close Date & Time

14 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**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

15 OCT 2020 08:01

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**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

16 OCT 2020 08:35

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**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

17 OCT 2020 06:25

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**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

18 OCT 2020 07:37

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**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

19 OCT 2020 08:14

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59



US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 07:05

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**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 ☐

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 11:06
PC Open Date & Time	13 OCT 2020 10:32
PC Close Date & Time	13 OCT 2020 13:02

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**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 ☐

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 06:32
PC Open Date & Time	13 OCT 2020 13:57
PC Close Date & Time	14 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**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 ☒

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 08:02
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 08:36
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**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 ☒

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 06:25
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

99 of 1981

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:17:58

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 07:38
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**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 ☒

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:17:58

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 08:14
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:17:58

**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 ☒



US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:17:58

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 07:05
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3372348

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:42:35

Generated On: 09 Jun 2021 17:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372348

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:45:05

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:42:35

Generated On: 09 Jun 2021 17:17:58

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 OCT 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372348

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:45:05

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:42:35

Generated On: 09 Jun 2021 17:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372348

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:45:05

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:08:27

Generated On: 09 Jun 2021 17:17:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3



US3372348

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 20:08:27

Generated On: 09 Jun 2021 17:17:58

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) \_\_\_\_\_

US3372348

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:08:27

Generated On: 09 Jun 2021 17:17:58

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.*

US3372348

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:08:27

Generated On: 09 Jun 2021 17:17:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 NOV 2020
Collection time (00:00-23:59)	09:19 (24 HR)
Collection date and time (derived)	9 NOV 2020 09:19

US3372348

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:08:26

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 06:58:51

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 09:16:46
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 00:03:01
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 07:23:24
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59



US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 08:33:07

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 07:46:18
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 08:46:26

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 12:03:39
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 00:02:59

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 19:43:15
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 00:03:14

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 00:02:21

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59



US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 11:24:40

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 11:28:09

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 09:44:19

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

<b>TIMEPOINT</b>	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 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	28 FEB 2021 20:52:16
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 08:42:51

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 00:03:53

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 09:21:41

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 09:54:53

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59



US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	05 APR 2021 11:24:40
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 12:10:02

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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

15 APR 2021 00:03:34

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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

22 APR 2021 07:15:24

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 08:13:54

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 243

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

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

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

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

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

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

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

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



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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21 JUN 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

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01 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUL 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	12 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

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09 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 SEP 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

16 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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"/>



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

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30 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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11 OCT 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	14 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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"/>



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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15 NOV 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

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18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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"/>

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	02 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	09 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2021 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JAN 2022 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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"/>

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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24 JAN 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 FEB 2022 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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°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 ☐



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

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03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

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10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 MAY 2022 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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"/>

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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"/>

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

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09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

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23 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	07 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2022 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59
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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

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01 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 SEP 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

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29 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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10 OCT 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

DAY 761

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

No ☐  
Yes ☐

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

No ☐  
Yes ☐

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

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

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

No ☐  
Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	20 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59
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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Open Date & Time](#)

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03 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2022 23:59

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US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

**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 ☐

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

US3372348

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:17:58

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"/>

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

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[Patient Cloud Close Date & Time](#)

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21 NOV 2022 23:59

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US3372348

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:17:58

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		28 FEB 2021 20:52:38



US3372348

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:42:35

Generated On: 09 Jun 2021 17:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372348

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:45:05

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:42:35

Generated On: 09 Jun 2021 17:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372348

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:45:05

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:42:35

Generated On: 09 Jun 2021 17:17:58

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 FEB 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372348

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:45:05

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 19:29:38

Generated On: 09 Jun 2021 17:17:58

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 MAR 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372348

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 19:29:38

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3372348

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 14:30:38

Generated On: 09 Jun 2021 17:17:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3372348

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 14:30:38

Generated On: 09 Jun 2021 17:17:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	29 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	08:51 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 08:51
Temperature ( <i>xxx.x</i> )	36.4 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> )	91 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372348

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 14:30:37

Generated On: 09 Jun 2021 17:17:58

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.*

US3372348

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 14:30:36

Generated On: 09 Jun 2021 17:17:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 MAR 2021

Collection time (00:00-23:59)

08:51 (24 HR)

Collection date and time (derived)

29 MAR 2021 08:51

US3372348

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 14:30:35

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3372348**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

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*

**US3372348**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372348

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:17:58

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



**US3372348**

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

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

**Generated On: 09 Jun 2021 17:17:58**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3372348

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

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:20:41

Generated On: 09 Jun 2021 17:17:58

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

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Visit date (dd MMM yyyy)	27 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"/>

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Folder OID	UNBLND_DECIDE
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US3372348

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

Form: Unblinding

Data signed: (b) (4) 14 Apr 2021 15:54:53

Generated On: 09 Jun 2021 17:17:58

Date of updated informed consent ( <i>dd MMM yyyy</i> )	27 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> )	27 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

US3372348

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 03:53:01

Generated On: 09 Jun 2021 17:17:58

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3372348

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 03:53:01

Generated On: 09 Jun 2021 17:17:58

Height	ND - Not Done
Weight	ND - Not Done
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)	27 JAN 2021
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 11:25
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	102 mmHg
Diastolic Blood Pressure units	MMHG

US3372348

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:53:01

Generated On: 09 Jun 2021 17:17:58

Height	ND - Not Done
Weight	ND - Not Done
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)	27 JAN 2021
Time of assessment (00:00-23:59)	12:45 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 12:45
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	186 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	106 mmHg
Diastolic Blood Pressure units	MMHG

US3372348

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

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:14:20

Generated On: 09 Jun 2021 17:17:58

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.*

US3372348

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

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:50:53

Generated On: 09 Jun 2021 17:17:58

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) 27 JAN 2021

What was the treatment time? (00:00-23:59) 12:15 (24 HR)

Treatment Date and Time (derived) 27 JAN 2021 12:15

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

What was the frequency of the study treatment dosing? ONCE

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



US3372348

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 00:10:26

Generated On: 09 Jun 2021 17:17:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00-23:59)

11:11 (24 HR)

Collection date and time (derived)

27 JAN 2021 11:11

US3372348

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 17:50:11

Generated On: 09 Jun 2021 17:17:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00 - 23:59)	11:09
Collection Date and Time (derived)	27 JAN 2021 11:09

US3372348

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

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:45:05

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:42:35

Generated On: 09 Jun 2021 17:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372348

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:45:05

Generated On: 09 Jun 2021 17:17:58

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

US3372348

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 21:01:17

Generated On: 09 Jun 2021 17:17:58

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

US3372348

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 21:01:17

Generated On: 09 Jun 2021 17:17:58

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)	13:05 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 13:05
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3372348

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 21:01:17

Generated On: 09 Jun 2021 17:17:58

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)	14:10 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 14:10
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG



US3372348

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 21:01:17

Generated On: 09 Jun 2021 17:17:58

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.*

US3372348

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 21:01:17

Generated On: 09 Jun 2021 17:17:58

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) 13:39 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 13:39

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

US3372348

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 21:01:17

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 19:29:38

Generated On: 09 Jun 2021 17:17:58

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*

US3372348

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 19:29:38

Generated On: 09 Jun 2021 17:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372348

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 14:30:33

Generated On: 09 Jun 2021 17:17:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3372348

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 14:30:33

Generated On: 09 Jun 2021 17:17:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	29 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	08:40 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 08:40
Temperature ( <i>xxx.x</i> )	36.4 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> )	91 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372348

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 14:30:32

Generated On: 09 Jun 2021 17:17:58

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.*



US3372348

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 14:30:31

Generated On: 09 Jun 2021 17:17:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	29 MAR 2021
Collection time ( <i>00:00-23:59</i> )	08:51 (24 HR)
Collection date and time (derived)	29 MAR 2021 08:51

US3372348

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 16:53:52

Generated On: 09 Jun 2021 17:17:58

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3372348

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

AEID

Adverse event

BACK PAIN - LEFT SIDED  
THORACOLUMBAR -  
INCREASED FROM BASELINE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3372348

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

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

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

AEID	USA-US056-2021-MRNA-1273-P30 1000014
Adverse event	MYOCARDIAL INFARCTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	02 APR 2021
Hospital Discharge Date (dd MMM yyyy)	04 APR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

Number of Days in ICU	3
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

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SUBJECT INFORMED THE SITE  
THAT THEY WERE ADMITTED  
TO THE HOSPITAL FOR  
MYOCARDIAL INFARCT ON  
02-APR-2021. DISCHARGED ON  
04-APR-2021. NO FURTHER  
AVAILABLE AT THIS TIME.  
MEDICAL RECORDS TO BE  
REQUESTED

---

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

---

US3372348

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

AEID	
Adverse event	LEFT ARM NUMBNESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

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

US3372348

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

AEID

Adverse event

SUBSTERNAL CHEST PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 APR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

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

US3372348

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 01:51:57

Generated On: 09 Jun 2021 17:17:58

---

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

Yes ☒

No ☐

---

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

---

US3372348

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Feb 2021 01:36:36

Generated On: 09 Jun 2021 17:17:58

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC LOWER BACK PAIN

Dose per administration 800

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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US3372348

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Feb 2021 01:36:36

Generated On: 09 Jun 2021 17:17:58

	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 DEC 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372348

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3372348

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
02 APR 2021	CHEST X-RAY	Adverse Event	
02 APR 2021	CARDIAC CATHETERIZATION / PCI	Adverse Event	



US3372348

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:17:58

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3372348

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:17:58

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 ☐

US3372348

Folder: SAE USA-US056-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

SAEID	USA-US056-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3

US3372348

Folder: SAE USA-US056-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

SAEID	USA-US056-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	06/APR/2021 14:07
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

US3372348

Folder: SAE USA-US056-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

SAEID	USA-US056-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	14/APR/2021 13:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3372348

Folder: SAE USA-US056-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Apr 2021 13:18:21

Generated On: 09 Jun 2021 17:17:58

SAEID	USA-US056-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	15/APR/2021 06:14
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

US3372348 (Prod: Palm Beach Research Center)

**US3372348**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:17:58**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:50:36
User entered 'US3372348'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Sep 2020 13:19:36



US3372348

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:17:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:20:41
User closed query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 13:54:23
Query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed.	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 18:10:12
' answered with 'data updated' (Site from DM).		
User opened query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 19:25:46
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	10 Sep 2020 19:53:32

**US3372348**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:20:41
User entered '07 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Sep 2020 13:19:37

**US3372348**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:20:41
User entered 'Clinic (Clinic)'	(b) (4) Peter Jacob (b) (4) (b) (4)	10 Sep 2020 19:53:32

**US3372348**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'SCRN'	System	10 Sep 2020 19:53:32

**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:15:25
User entered (b) (6) 1961'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Sep 2020 13:19:38

**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:15:25
User entered '59'	(b) (4) Peter Jacob (b) (4) (b) (4)	10 Sep 2020 19:53:41

**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'YEARS'	System	10 Sep 2020 19:53:41

**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '59'	System	15 Sep 2020 14:11:22



**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:15:25
User entered 'Male (M)'	(b) (4) Peter Jacob (b) (4) (b) (4)	10 Sep 2020 19:53:41

**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:15:25
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Peter Jacob (b) (4)	10 Sep 2020 19:53:41

**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:15:25
User entered 'I'	(b) (4) Peter Jacob (b) (4) (b) (4)	10 Sep 2020 19:53:41

**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:15:25
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	10 Sep 2020 19:53:41

**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:15:25
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	10 Sep 2020 19:53:41

**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:15:25
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	10 Sep 2020 19:53:41

**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:15:25
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	10 Sep 2020 19:53:41

**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:15:25
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	10 Sep 2020 19:53:41



**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:15:25
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	10 Sep 2020 19:53:41

**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:15:25
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	10 Sep 2020 19:53:41

**US3372348**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:17:58**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:15:25
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	10 Sep 2020 19:53:41

**US3372348**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:17:58**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:33:22
User entered '7 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:11:22

**US3372348**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'Sep 2020'	System	15 Sep 2020 14:11:22

**US3372348**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '2020'	System	15 Sep 2020 14:11:22

**US3372348**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:17:58**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:33:22
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:11:22

US3372348

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:33:22
User closed query 'Per CDM: Please indicate if subject was enrolled in the study and complete the appropriate eCRF forms as indicated in the CCGs pages 15-16. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 22:00:46
Query 'Per CDM: Please indicate if subject was enrolled in the study and complete the appropriate eCRF forms as indicated in the CCGs pages 15-16. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	30 Sep 2020 20:57:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 14:11:22
User opened query 'Per CDM: Please indicate if subject was enrolled in the study and complete the appropriate eCRF forms as indicated in the CCGs pages 15-16. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:28:51



**US3372348**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:17:58**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:33:22
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:11:22

**US3372348**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:17:58**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:33:22
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:11:22

**US3372348**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:17:58**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:33:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:11:22

**US3372348**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:17:58**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:33:22
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Sep 2020 13:19:37

**US3372348**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:17:58**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'I'	System	15 Sep 2020 14:11:32

**US3372348**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:26:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:11:32

US3372348

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:17:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:58:34
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 17:46:46

US3372348

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:53:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:53:49
Data point term sent to Coder	System	28 Sep 2020 17:52:14
User entered 'myocardial infarction'	Peter Jacob (b) (4)	28 Sep 2020 17:51:52



**US3372348**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'un UNK 2012'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:51:52

**US3372348**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:51:52

**US3372348**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:51:52

**US3372348**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:17:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'un UNK 2012'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:51:52

**US3372348**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:51:52

**US3372348**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'Jan 2012'	System	28 Sep 2020 17:51:52

**US3372348**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '2012'	System	28 Sep 2020 17:51:52

**US3372348**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'Jan 2012'	System	28 Sep 2020 17:51:52



**US3372348**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '2012'	System	28 Sep 2020 17:51:52

US3372348

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: Coronary artery bypass graft - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:53:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:53:48
Data point term sent to Coder	System	28 Sep 2020 17:52:14
User entered 'coronary artery bypass graft'	Peter Jacob (b) (4)	28 Sep 2020 17:52:09

**US3372348**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'un UNK 2012'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:09

**US3372348**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:09

**US3372348**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:09

**US3372348**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:17:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'un UNK 2012'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:09

**US3372348**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:09

**US3372348**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'Jan 2012'	System	28 Sep 2020 17:52:09



**US3372348**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '2012'	System	28 Sep 2020 17:52:09

**US3372348**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'Jan 2012'	System	28 Sep 2020 17:52:09

**US3372348**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '2012'	System	28 Sep 2020 17:52:09

US3372348

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:54:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:54:37
Data point term sent to Coder	System	28 Sep 2020 17:53:15
User entered 'coronary artery disease'	Peter Jacob (b) (4)	28 Sep 2020 17:52:22

**US3372348**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'un UNK 2012'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:22

**US3372348**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:22

**US3372348**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:22

**US3372348**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:17:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:22



**US3372348**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:22

**US3372348**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'Jan 2012'	System	28 Sep 2020 17:52:22

**US3372348**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '2012'	System	28 Sep 2020 17:52:22

**US3372348**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered empty.	System	28 Sep 2020 17:52:22

**US3372348**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered empty.	System	28 Sep 2020 17:52:22

US3372348

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 09:27:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 09:27:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:54:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:54:37
Data point term sent to Coder	System	28 Sep 2020 17:53:15
User entered 'chronic lower back pain'	Peter Jacob (b) (4)	28 Sep 2020 17:52:33

**US3372348**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:33

**US3372348**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:33



**US3372348**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:33

**US3372348**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:17:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:33

**US3372348**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:33

**US3372348**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'Jan 2019'	System	28 Sep 2020 17:52:33

**US3372348**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '2019'	System	28 Sep 2020 17:52:33

**US3372348**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered empty.	System	28 Sep 2020 17:52:33

**US3372348**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered empty.	System	28 Sep 2020 17:52:33

US3372348

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:54:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 17:54:37
Data point term sent to Coder	System	28 Sep 2020 17:53:15
User entered 'environmental allergies'	Peter Jacob (b) (4)	28 Sep 2020 17:52:50



**US3372348**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'un UNK 2017'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:50

**US3372348**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:17:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:50

**US3372348**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:17:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:50

**US3372348**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:17:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:50

**US3372348**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:17:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:52:50

**US3372348**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'Jan 2017'	System	28 Sep 2020 17:52:50

**US3372348**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '2017'	System	28 Sep 2020 17:52:50

**US3372348**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered empty.	System	28 Sep 2020 17:52:50



**US3372348**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered empty.	System	28 Sep 2020 17:52:50

US3372348

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Tendon rupture, LLT: Biceps tendon rupture - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 05:30:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 05:30:51
Data point term sent to Coder	System	28 Sep 2020 17:53:15
User entered 'partial left biceps tendon rupture'	Peter Jacob (b) (4)	28 Sep 2020 17:53:07

**US3372348**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'un UNK 2017'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 17:53:07

**US3372348**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:17:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:07

**US3372348**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:17:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:07

**US3372348**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:17:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered 'un UNK 2017'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:07

**US3372348**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:17:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:42:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:07

**US3372348**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'Jan 2017'	System	28 Sep 2020 17:53:07



**US3372348**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '2017'	System	28 Sep 2020 17:53:07

**US3372348**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'Jan 2017'	System	28 Sep 2020 17:53:07

**US3372348**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '2017'	System	28 Sep 2020 17:53:07

**US3372348**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:36:49
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:48

US3372348

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:36:49
User entered '07 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:48

**US3372348**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:36:49
User entered '09:44'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:48

**US3372348**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '07 Sep 2020 09:44'	System	28 Sep 2020 17:53:48

**US3372348**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:36:49
User entered '176' cm	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 17:53:48
DataPoint set to visible.	(b) (4) System	15 Sep 2020 14:11:32



US3372348

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:58

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:36:49
User entered '88.9' kg	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 17:53:48
DataPoint set to visible.	(b) (4) System	15 Sep 2020 14:11:32

**US3372348**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '28.69964'	System	28 Sep 2020 17:53:48
DataPoint set to visible.	System	15 Sep 2020 14:11:32

**US3372348**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'kg/m2'	System	28 Sep 2020 17:53:48
DataPoint set to visible.	System	15 Sep 2020 14:11:32

US3372348

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:36:49
User entered '37' C	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:48

**US3372348**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:36:49
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:48

**US3372348**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:36:49
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:48

**US3372348**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:36:49
User entered '74'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:48

**US3372348**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'bpm'	System	28 Sep 2020 17:53:48



US3372348

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:36:49
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:48

US3372348

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'breaths/min'	System	28 Sep 2020 17:53:48

US3372348

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:36:49
User closed query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 07:05:08
Query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' answered with 'NCs' (Site from System).	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:01
User opened query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System).	System	28 Sep 2020 17:53:48
User entered '158'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:48

**US3372348**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'mmHg'	System	28 Sep 2020 17:53:48

US3372348

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:36:49
User entered '93'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:48

**US3372348**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'mmHg'	System	28 Sep 2020 17:53:48

**US3372348**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59

**US3372348**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59



US3372348

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:14:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:55

**US3372348**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:17:58**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:14:20
User entered '07 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:53:55

US3372348

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:58

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

US3372348

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:58

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

US3372348

Folder: Screening

Form: Risk of Exposure

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**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

US3372348

Folder: Screening

Form: Risk of Exposure

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**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

US3372348

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:58

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

US3372348

Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21



US3372348

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:58

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

US3372348

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:17:58

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

US3372348

Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 17:54:26
User entered 'No (N)' reason for change: Data Entry Error	Peter Jacob (b) (4)	28 Sep 2020 17:54:26
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	28 Sep 2020 17:54:21
	Peter Jacob (b) (4)	28 Sep 2020 17:54:21
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

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Folder: Screening

Form: Risk of Exposure

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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

**US3372348**

**Folder: Screening**

**Form: Risk of Exposure**

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**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21



US3372348

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

US3372348

Folder: Screening

Form: Risk of Exposure

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**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered '0'	Peter Jacob (b) (4)	28 Sep 2020 17:54:21

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Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered 'I'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

US3372348

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

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Folder: Screening

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

US3372348

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:24:41
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:54:21

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:20:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:37:06



**US3372348**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:20:41
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:37:06

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:20:41
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:37:06

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'VISIT1'	System	15 Sep 2020 13:37:06

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:21
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:41:48
User entered '15 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 13:39:39

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:21
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:41:48
User entered '113912'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 13:39:39

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:21
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:41:48
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Sep 2020 13:39:39

US3372348

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:58

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)	30 Apr 2021 19:16:21
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:41:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:41:15

US3372348

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:17:58

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)	30 Apr 2021 19:16:21
User closed query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 03:03:09
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:41:48
Query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' answered with 'cohort cannot be updated ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 21:49:44
User opened query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 19:27:34
Query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	26 Mar 2021 19:27:28
User opened query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	15 Sep 2020 13:41:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 13:41:15



**US3372348**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:21
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:41:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:41:15

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:17:58**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:21
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:41:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:41:15

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:17:58**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:21
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:41:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:41:15

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:17:58**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:16:21
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:41:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 17:54:37
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:34:21
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:34:20

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:17:58**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '176' cm	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '88.1' kg	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '176' cm	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '88.1' kg	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09



US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '09:23'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '15 Sep 2020 09:23'	System	28 Sep 2020 17:55:09

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '36.7' C	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 17:55:09

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09



**US3372348**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '98'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'bpm'	System	28 Sep 2020 17:55:09

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '14'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'breaths/min'	System	28 Sep 2020 17:55:09

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '162'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'mmHg'	System	28 Sep 2020 17:55:09

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '101'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'mmHg'	System	28 Sep 2020 17:55:09



US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '176' cm	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '88.1' kg	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:09

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:28

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:28

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:28

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '11:00'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:28

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '15 Sep 2020 11:00'	System	28 Sep 2020 17:55:28

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '36.6' C	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 17:55:28



US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:28

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:28

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '80'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:28

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'bpm'	System	28 Sep 2020 17:55:28

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:28

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'breaths/min'	System	28 Sep 2020 17:55:28

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '175'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:28

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'mmHg'	System	28 Sep 2020 17:55:28



US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '103'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:28

US3372348

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'mmHg'	System	28 Sep 2020 17:55:28

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:17:58**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:14:20
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:33

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:17:58**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:14:20
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:33

US3372348

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:50:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:27:22

US3372348

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:50:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:27:22

US3372348

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:50:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:27:22

US3372348

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 14:27:22



US3372348

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:50:53
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:27:22

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:50:53
User entered '10:25'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:27:22

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '15 Sep 2020 10:25'	System	15 Sep 2020 14:27:22

US3372348

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:50:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:27:22

US3372348

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'ONCE'	System	15 Sep 2020 14:27:22

US3372348

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:10:26
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 17:55:42

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:10:26
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 17:55:42



**US3372348**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:10:26
User entered '09:43'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:42

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '15 Sep 2020 09:43'	System	28 Sep 2020 17:55:42

US3372348

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:17:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:27:24
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:51

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:51

US3372348

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:17:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:27:24
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 17:55:51

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:27:24
User entered '09:42'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:51

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '15 Sep 2020 09:42'	System	28 Sep 2020 17:55:51

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:51



**US3372348**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:27:24
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:51

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:17:58**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:27:24
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:51

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered empty.	System	28 Sep 2020 17:55:51

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:45:05
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:55:54

**US3372348**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered '1'	System	28 Sep 2020 17:55:54

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:58:17', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1ffbd28d-2e75-4e16-941c-527f0f661723' User entered 'Yes (Y)'	System	15 Sep 2020 14:59:06
	System	15 Sep 2020 14:59:06

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:58:39', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1ffbd28d-2e75-4e16-941c-527f0f661723' User entered '97.9'	System	15 Sep 2020 14:59:06
	System	15 Sep 2020 14:59:06



US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:58:50', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1ffbd28d-2e75-4e16-941c-527f0f661723'	System	15 Sep 2020 14:59:06
User entered 'No (N)'	System	15 Sep 2020 14:59:06

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:58:57', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1ffbd28d-2e75-4e16-941c-527f0f661723' User entered '15 Sep 2020 10:58'	System	15 Sep 2020 14:59:06
	System	15 Sep 2020 14:59:06

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Sep 2020 10:45'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Sep 2020 13:15'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:50:05', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '88f7f5ee-33d0-4ac3-ab95-7149e517d424' User entered 'Yes (Y)'	System	16 Sep 2020 11:50:38
	System	16 Sep 2020 11:50:38

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:50:20', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '88f7f5ee-33d0-4ac3-ab95-7149e517d424' User entered '97.7'	System	16 Sep 2020 11:50:38
	System	16 Sep 2020 11:50:38

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:50:27', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '88f7f5ee-33d0-4ac3-ab95-7149e517d424' User entered 'No (N)'	System	16 Sep 2020 11:50:38
	System	16 Sep 2020 11:50:38



**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:50:34', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '88f7f5ee-33d0-4ac3-ab95-7149e517d424' User entered '16 Sep 2020 07:50'	System	16 Sep 2020 11:50:38
	System	16 Sep 2020 11:50:38

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Sep 2020 14:10'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 2'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:41:13', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'a80fe783-dc5d-479e-8adf-77d81f918c0c' User entered 'Yes (Y)'	System	16 Sep 2020 17:42:03
	System	16 Sep 2020 17:42:03

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:41:42', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'a80fe783-dc5d-479e-8adf-77d81f918c0c' User entered '97.8'	System	16 Sep 2020 17:42:03
	System	16 Sep 2020 17:42:03

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:41:50', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'a80fe783-dc5d-479e-8adf-77d81f918c0c'	System	16 Sep 2020 17:42:03
User entered 'No (N)'	System	16 Sep 2020 17:42:03

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:41:59', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'a80fe783-dc5d-479e-8adf-77d81f918c0c' User entered '16 Sep 2020 13:41'	System	16 Sep 2020 17:42:03
	System	16 Sep 2020 17:42:03



**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 3'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:36:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8623719c-39f7-42d9-8d19-12976ec5ce25'	System	17 Sep 2020 23:36:56
User entered 'Yes (Y)'	System	17 Sep 2020 23:36:56

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:36:33', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8623719c-39f7-42d9-8d19-12976ec5ce25' User entered '97.7'	System	17 Sep 2020 23:36:56
	System	17 Sep 2020 23:36:56

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:36:43', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8623719c-39f7-42d9-8d19-12976ec5ce25'	System	17 Sep 2020 23:36:56
User entered 'No (N)'	System	17 Sep 2020 23:36:56

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:36:54', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8623719c-39f7-42d9-8d19-12976ec5ce25'	System	17 Sep 2020 23:36:56
User entered '17 Sep 2020 19:36'	System	17 Sep 2020 23:36:56

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 14:27:22



US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 4'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:19:57', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b6fe7ce6-3915-4401-bdb3-27cb12112ffe' User entered 'Yes (Y)'	System	18 Sep 2020 21:20:34
	System	18 Sep 2020 21:20:34

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:20:13', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b6fe7ce6-3915-4401-bdb3-27cb12112ffe' User entered '97.7'	System	18 Sep 2020 21:20:34
	System	18 Sep 2020 21:20:34

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:20:24', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b6fe7ce6-3915-4401-bdb3-27cb12112ffe'	System	18 Sep 2020 21:20:34
User entered 'No (N)'	System	18 Sep 2020 21:20:34

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:20:29', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b6fe7ce6-3915-4401-bdb3-27cb12112ffe' User entered '18 Sep 2020 17:20'	System	18 Sep 2020 21:20:34
	System	18 Sep 2020 21:20:34

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 14:27:22



US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 5'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:41:52', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c04b22c6-174b-454a-a54a-169a615a994f' User entered 'Yes (Y)'	System	19 Sep 2020 18:42:40
	System	19 Sep 2020 18:42:40

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:42:06', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c04b22c6-174b-454a-a54a-169a615a994f' User entered '97.8'	System	19 Sep 2020 18:42:40
	System	19 Sep 2020 18:42:40

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:42:34', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c04b22c6-174b-454a-a54a-169a615a994f' User entered 'No (N)'	System	19 Sep 2020 18:42:40
	System	19 Sep 2020 18:42:40

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:42:39', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c04b22c6-174b-454a-a54a-169a615a994f' User entered '19 Sep 2020 14:42'	System	19 Sep 2020 18:42:40
	System	19 Sep 2020 18:42:40

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 6'	System	15 Sep 2020 14:27:22



US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:13:22', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1bb1afb4-3ce1-4eb7-a509-869d27d9811a' User entered 'Yes (Y)'	System	20 Sep 2020 23:14:25
	System	20 Sep 2020 23:14:25

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:13:59', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1bb1afb4-3ce1-4eb7-a509-869d27d9811a' User entered '97.8'	System	20 Sep 2020 23:14:25
	System	20 Sep 2020 23:14:25

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:14:03', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1bb1afb4-3ce1-4eb7-a509-869d27d9811a' User entered 'Yes (Y)'	System	20 Sep 2020 23:14:25
	System	20 Sep 2020 23:14:25

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject was contacted. States they did not use any pain medication, this is a diary entry error' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 12:26:55
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:14:19', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1bb1afb4-3ce1-4eb7-a509-869d27d9811a' User entered '1'	Mary Sergalis (b) (4)	14 Oct 2020 20:28:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	20 Sep 2020 23:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:14:19', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1bb1afb4-3ce1-4eb7-a509-869d27d9811a' User entered '1'	System	20 Sep 2020 23:14:25
User entered '1'	System	20 Sep 2020 23:14:25

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:17:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:14:19', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1bb1afb4-3ce1-4eb7-a509-869d27d9811a' User entered '0'	System	20 Sep 2020 23:14:25
	System	20 Sep 2020 23:14:25

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:14:23', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1bb1afb4-3ce1-4eb7-a509-869d27d9811a' User entered '20 Sep 2020 19:14'	System	20 Sep 2020 23:14:25
	System	20 Sep 2020 23:14:25

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 14:27:22



**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 7'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:00:59', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8118550d-cf2b-4776-8750-851ede9eb97d' User entered 'Yes (Y)'	System	21 Sep 2020 16:05:25
	System	21 Sep 2020 16:05:25

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:01:14', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8118550d-cf2b-4776-8750-851ede9eb97d' User entered '97.8'	System	21 Sep 2020 16:05:25
	System	21 Sep 2020 16:05:25

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:01:23', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8118550d-cf2b-4776-8750-851ede9eb97d' User entered 'No (N)'	System	21 Sep 2020 16:05:25
	System	21 Sep 2020 16:05:25

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:01:28', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8118550d-cf2b-4776-8750-851ede9eb97d' User entered '21 Sep 2020 12:01'	System	21 Sep 2020 16:05:25
	System	21 Sep 2020 16:05:25

US3372348

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 14:27:22



US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:56:06', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'd75d67c0-74f5-4dcb-ae66-71960dfbf291'	System	15 Sep 2020 14:56:43
User entered 'None (1)'	System	15 Sep 2020 14:56:43

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:56:16', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'd75d67c0-74f5-4dcb-ae66-71960dfbf291'	System	15 Sep 2020 14:56:43
User entered 'No (N)'	System	15 Sep 2020 14:56:43

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:56:22', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'd75d67c0-74f5-4dcb-ae66-71960dfbf291' User entered 'No (N)'	System	15 Sep 2020 14:56:43
	System	15 Sep 2020 14:56:43

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:56:31', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'd75d67c0-74f5-4dcb-ae66-71960dfbf291'	System	15 Sep 2020 14:56:43
User entered 'None (1)'	System	15 Sep 2020 14:56:43

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:56:39', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'd75d67c0-74f5-4dcb-ae66-71960dfbf291' User entered '15 Sep 2020 10:56'	System	15 Sep 2020 14:56:43
	System	15 Sep 2020 14:56:43

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Sep 2020 10:45'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Sep 2020 13:15'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 14:27:22



US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:50:47', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '524684d2-e69e-46fb-bc5d-13be635abe59' User entered 'None (1)'	System	16 Sep 2020 11:51:24
	System	16 Sep 2020 11:51:24

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:50:54', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '524684d2-e69e-46fb-bc5d-13be635abe59' User entered 'No (N)'	System	16 Sep 2020 11:51:24
	System	16 Sep 2020 11:51:24

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:50:58', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '524684d2-e69e-46fb-bc5d-13be635abe59' User entered 'No (N)'	System	16 Sep 2020 11:51:24
	System	16 Sep 2020 11:51:24

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:51:12', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '524684d2-e69e-46fb-bc5d-13be635abe59' User entered 'None (1)'	System	16 Sep 2020 11:51:24
	System	16 Sep 2020 11:51:24

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:51:21', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '524684d2-e69e-46fb-bc5d-13be635abe59'	System	16 Sep 2020 11:51:24
User entered '16 Sep 2020 07:51'	System	16 Sep 2020 11:51:24

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Sep 2020 14:10'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 2'	System	15 Sep 2020 14:27:22



US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:42:09', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b3b296de-4820-4fbf-8872-d1116572bb22'	System	16 Sep 2020 17:42:32
User entered 'None (1)'	System	16 Sep 2020 17:42:32

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:42:13', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b3b296de-4820-4fbf-8872-d1116572bb22'	System	16 Sep 2020 17:42:32
User entered 'No (N)'	System	16 Sep 2020 17:42:32

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:42:17', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b3b296de-4820-4fbf-8872-d1116572bb22'	System	16 Sep 2020 17:42:32
User entered 'No (N)'	System	16 Sep 2020 17:42:32

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:42:23', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b3b296de-4820-4fbf-8872-d1116572bb22'	System	16 Sep 2020 17:42:32
User entered 'None (1)'	System	16 Sep 2020 17:42:32

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:42:27', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b3b296de-4820-4fbf-8872-d1116572bb22' User entered '16 Sep 2020 13:42'	System	16 Sep 2020 17:42:32
	System	16 Sep 2020 17:42:32

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 3'	System	15 Sep 2020 14:27:22



US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:37:03', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '4f88b863-b1f1-4f00-a768-a4d6beb0aaa2'	System	17 Sep 2020 23:37:36
User entered 'None (1)'	System	17 Sep 2020 23:37:36

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:37:08', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '4f88b863-b1f1-4f00-a768-a4d6beb0aaa2'	System	17 Sep 2020 23:37:36
User entered 'No (N)'	System	17 Sep 2020 23:37:36

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:37:14', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '4f88b863-b1f1-4f00-a768-a4d6beb0aaa2'	System	17 Sep 2020 23:37:36
User entered 'No (N)'	System	17 Sep 2020 23:37:36

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:37:24', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '4f88b863-b1f1-4f00-a768-a4d6beb0aaa2'	System	17 Sep 2020 23:37:36
User entered 'None (1)'	System	17 Sep 2020 23:37:36

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:37:32', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '4f88b863-b1f1-4f00-a768-a4d6beb0aaa2'	System	17 Sep 2020 23:37:36
User entered '17 Sep 2020 19:37'	System	17 Sep 2020 23:37:36

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 4'	System	15 Sep 2020 14:27:22



US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:20:37', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '33171c0d-c8b3-453b-ab02-bb1979162364'	System	18 Sep 2020 21:21:12
User entered 'None (1)'	System	18 Sep 2020 21:21:12

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:20:41', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '33171c0d-c8b3-453b-ab02-bb1979162364' User entered 'No (N)'	System	18 Sep 2020 21:21:12
	System	18 Sep 2020 21:21:12

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:20:50', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '33171c0d-c8b3-453b-ab02-bb1979162364' User entered 'No (N)'	System	18 Sep 2020 21:21:12
	System	18 Sep 2020 21:21:12

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:21:02', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '33171c0d-c8b3-453b-ab02-bb1979162364'	System	18 Sep 2020 21:21:12
User entered 'None (1)'	System	18 Sep 2020 21:21:12

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:21:08', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '33171c0d-c8b3-453b-ab02-bb1979162364' User entered '18 Sep 2020 17:21'	System	18 Sep 2020 21:21:12
	System	18 Sep 2020 21:21:12

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 5'	System	15 Sep 2020 14:27:22



US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:42:46', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'a2e4befc-fd5d-42c8-90f7-43896ce9feee'	System	19 Sep 2020 18:43:04
User entered 'None (1)'	System	19 Sep 2020 18:43:04

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:42:49', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'a2e4befc-fd5d-42c8-90f7-43896ce9feee' User entered 'No (N)'	System	19 Sep 2020 18:43:04
	System	19 Sep 2020 18:43:04

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:42:54', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'a2e4befc-fd5d-42c8-90f7-43896ce9feee'	System	19 Sep 2020 18:43:04
User entered 'No (N)'	System	19 Sep 2020 18:43:04

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:42:57', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'a2e4befc-fd5d-42c8-90f7-43896ce9feee'	System	19 Sep 2020 18:43:04
User entered 'None (1)'	System	19 Sep 2020 18:43:04

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:43:01', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'a2e4befc-fd5d-42c8-90f7-43896ce9feee' User entered '19 Sep 2020 14:43'	System	19 Sep 2020 18:43:04
	System	19 Sep 2020 18:43:04

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 6'	System	15 Sep 2020 14:27:22



US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:14:32', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '39442428-583b-4c1b-a50a-85b543933232'	System	20 Sep 2020 23:14:56
User entered 'None (1)'	System	20 Sep 2020 23:14:56

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:14:38', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '39442428-583b-4c1b-a50a-85b543933232'	System	20 Sep 2020 23:14:56
User entered 'No (N)'	System	20 Sep 2020 23:14:56

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:14:43', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '39442428-583b-4c1b-a50a-85b543933232' User entered 'No (N)'	System	20 Sep 2020 23:14:56
	System	20 Sep 2020 23:14:56

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:14:48', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '39442428-583b-4c1b-a50a-85b543933232'	System	20 Sep 2020 23:14:56
User entered 'None (1)'	System	20 Sep 2020 23:14:56

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:14:51', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '39442428-583b-4c1b-a50a-85b543933232'	System	20 Sep 2020 23:14:56
User entered '20 Sep 2020 19:14'	System	20 Sep 2020 23:14:56

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 7'	System	15 Sep 2020 14:27:22



US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:01:42', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '190ec66a-17f8-4d27-9e26-ee576e0ab4f9'	System	21 Sep 2020 16:14:23
User entered 'None (1)'	System	21 Sep 2020 16:14:23

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:01:51', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '190ec66a-17f8-4d27-9e26-ee576e0ab4f9' User entered 'No (N)'	System	21 Sep 2020 16:14:23
	System	21 Sep 2020 16:14:23

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:01:59', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '190ec66a-17f8-4d27-9e26-ee576e0ab4f9' User entered 'No (N)'	System	21 Sep 2020 16:14:23
	System	21 Sep 2020 16:14:23

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:02:06', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '190ec66a-17f8-4d27-9e26-ee576e0ab4f9' User entered 'None (1)'	System	21 Sep 2020 16:14:23
	System	21 Sep 2020 16:14:23

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:02:24', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '190ec66a-17f8-4d27-9e26-ee576e0ab4f9' User entered '21 Sep 2020 12:02'	System	21 Sep 2020 16:14:23
	System	21 Sep 2020 16:14:23

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 14:27:22



US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:54:50', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b2aee3a8-b487-44df-b6de-510dd6cacfcc' User entered 'None (0)'	System	15 Sep 2020 14:55:59
	System	15 Sep 2020 14:55:59

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:55:09', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b2aee3a8-b487-44df-b6de-510dd6cacfcc' User entered 'None (0)'	System	15 Sep 2020 14:55:59
	System	15 Sep 2020 14:55:59

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:55:19', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b2aee3a8-b487-44df-b6de-510dd6cacfcc' User entered 'None (0)'	System	15 Sep 2020 14:55:59
	System	15 Sep 2020 14:55:59

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:55:26', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b2aee3a8-b487-44df-b6de-510dd6cacfcc' User entered 'None (0)'	System	15 Sep 2020 14:55:59
	System	15 Sep 2020 14:55:59

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:55:31', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b2aee3a8-b487-44df-b6de-510dd6cacfcc' User entered 'None (0)'	System	15 Sep 2020 14:55:59
	System	15 Sep 2020 14:55:59

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:55:35', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b2aee3a8-b487-44df-b6de-510dd6cacfcc' User entered 'None (0)'	System	15 Sep 2020 14:55:59
	System	15 Sep 2020 14:55:59

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:55:48', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b2aee3a8-b487-44df-b6de-510dd6cacfcc' User entered 'No (N)'	System	15 Sep 2020 14:55:59
	System	15 Sep 2020 14:55:59

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-15T10:55:56', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b2aee3a8-b487-44df-b6de-510dd6cacfcc' User entered '15 Sep 2020 10:55'	System	15 Sep 2020 14:55:59
	System	15 Sep 2020 14:55:59



**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Sep 2020 10:45'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Sep 2020 13:15'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:51:31', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '32e532f7-76f3-42c2-8345-33d994365473' User entered 'None (0)'	System	16 Sep 2020 11:52:58
	System	16 Sep 2020 11:52:58

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:51:40', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '32e532f7-76f3-42c2-8345-33d994365473' User entered 'None (0)'	System	16 Sep 2020 11:52:58
	System	16 Sep 2020 11:52:58

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:51:56', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '32e532f7-76f3-42c2-8345-33d994365473' User entered 'None (0)'	System	16 Sep 2020 11:52:58
	System	16 Sep 2020 11:52:58

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:52:05', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '32e532f7-76f3-42c2-8345-33d994365473' User entered 'None (0)'	System	16 Sep 2020 11:52:58
	System	16 Sep 2020 11:52:58

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:52:30', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '32e532f7-76f3-42c2-8345-33d994365473' User entered 'None (0)'	System	16 Sep 2020 11:52:58
	System	16 Sep 2020 11:52:58



**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:52:35', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '32e532f7-76f3-42c2-8345-33d994365473' User entered 'None (0)'	System	16 Sep 2020 11:52:58
	System	16 Sep 2020 11:52:58

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:52:49', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '32e532f7-76f3-42c2-8345-33d994365473' User entered 'No (N)'	System	16 Sep 2020 11:52:58
	System	16 Sep 2020 11:52:58

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T07:52:53', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '32e532f7-76f3-42c2-8345-33d994365473' User entered '16 Sep 2020 07:52'	System	16 Sep 2020 11:52:58
	System	16 Sep 2020 11:52:58

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Sep 2020 14:10'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 2'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:42:33', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c285ef96-1bb0-4271-b580-104e80872142' User entered 'None (0)'	System	16 Sep 2020 17:43:15
	System	16 Sep 2020 17:43:15

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:42:38', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c285ef96-1bb0-4271-b580-104e80872142' User entered 'None (0)'	System	16 Sep 2020 17:43:15
	System	16 Sep 2020 17:43:15



US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:42:46', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c285ef96-1bb0-4271-b580-104e80872142' User entered 'None (0)'	System	16 Sep 2020 17:43:15
	System	16 Sep 2020 17:43:15

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:42:51', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c285ef96-1bb0-4271-b580-104e80872142' User entered 'None (0)'	System	16 Sep 2020 17:43:15
	System	16 Sep 2020 17:43:15

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:42:55', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c285ef96-1bb0-4271-b580-104e80872142' User entered 'None (0)'	System	16 Sep 2020 17:43:15
	System	16 Sep 2020 17:43:15

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:42:59', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c285ef96-1bb0-4271-b580-104e80872142' User entered 'None (0)'	System	16 Sep 2020 17:43:15
	System	16 Sep 2020 17:43:15

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:43:09', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c285ef96-1bb0-4271-b580-104e80872142' User entered 'No (N)'	System	16 Sep 2020 17:43:15
	System	16 Sep 2020 17:43:15

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-16T13:43:12', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c285ef96-1bb0-4271-b580-104e80872142' User entered '16 Sep 2020 13:43'	System	16 Sep 2020 17:43:15
	System	16 Sep 2020 17:43:15

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 14:27:22



**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 3'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:37:39', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '83af4dfa-c99f-47c3-90c9-49322d440613' User entered 'None (0)'	System	17 Sep 2020 23:38:32
	System	17 Sep 2020 23:38:32

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:37:50', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '83af4dfa-c99f-47c3-90c9-49322d440613' User entered 'None (0)'	System	17 Sep 2020 23:38:32
	System	17 Sep 2020 23:38:32

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:38:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '83af4dfa-c99f-47c3-90c9-49322d440613' User entered 'None (0)'	System	17 Sep 2020 23:38:32
	System	17 Sep 2020 23:38:32

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:38:05', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '83af4dfa-c99f-47c3-90c9-49322d440613' User entered 'None (0)'	System	17 Sep 2020 23:38:32
	System	17 Sep 2020 23:38:32

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:38:10', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '83af4dfa-c99f-47c3-90c9-49322d440613' User entered 'None (0)'	System	17 Sep 2020 23:38:32
	System	17 Sep 2020 23:38:32

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:38:15', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '83af4dfa-c99f-47c3-90c9-49322d440613' User entered 'None (0)'	System	17 Sep 2020 23:38:32
	System	17 Sep 2020 23:38:32

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:38:24', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '83af4dfa-c99f-47c3-90c9-49322d440613'	System	17 Sep 2020 23:38:32
User entered 'No (N)'	System	17 Sep 2020 23:38:32



**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-17T19:38:28', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '83af4dfa-c99f-47c3-90c9-49322d440613' User entered '17 Sep 2020 19:38'	System	17 Sep 2020 23:38:32
	System	17 Sep 2020 23:38:32

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 4'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:21:24', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '6fbd3c17-6fc8-448b-bcc7-f96a1ec0eca6' User entered 'None (0)'	System	18 Sep 2020 21:22:49
	System	18 Sep 2020 21:22:49

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:21:59', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '6fbd3c17-6fc8-448b-bcc7-f96a1ec0eca6' User entered 'None (0)'	System	18 Sep 2020 21:22:49
	System	18 Sep 2020 21:22:49

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:22:13', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '6fbd3c17-6fc8-448b-bcc7-f96a1ec0eca6' User entered 'None (0)'	System	18 Sep 2020 21:22:49
	System	18 Sep 2020 21:22:49

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:22:26', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '6fbd3c17-6fc8-448b-bcc7-f96a1ec0eca6' User entered 'None (0)'	System	18 Sep 2020 21:22:49
	System	18 Sep 2020 21:22:49



US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:22:32', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '6fbd3c17-6fc8-448b-bcc7-f96a1ec0eca6' User entered 'None (0)'	System	18 Sep 2020 21:22:49
	System	18 Sep 2020 21:22:49

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:22:35', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '6fbd3c17-6fc8-448b-bcc7-f96a1ec0eca6' User entered 'None (0)'	System	18 Sep 2020 21:22:49
	System	18 Sep 2020 21:22:49

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:22:40', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '6fbd3c17-6fc8-448b-bcc7-f96a1ec0eca6' User entered 'No (N)'	System	18 Sep 2020 21:22:49
	System	18 Sep 2020 21:22:49

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-18T17:22:44', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '6fbd3c17-6fc8-448b-bcc7-f96a1ec0eca6' User entered '18 Sep 2020 17:22'	System	18 Sep 2020 21:22:49
	System	18 Sep 2020 21:22:49

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 5'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:43:09', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ee8c2b09-5d1d-4d1c-9c9c-a64aaace2cb2' User entered 'None (0)'	System	19 Sep 2020 18:43:38
	System	19 Sep 2020 18:43:38



US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:43:12', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ee8c2b09-5d1d-4d1c-9c9c-a64aaace2cb2' User entered 'None (0)'	System	19 Sep 2020 18:43:38
	System	19 Sep 2020 18:43:38

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:43:15', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ee8c2b09-5d1d-4d1c-9c9c-a64aaace2cb2' User entered 'None (0)'	System	19 Sep 2020 18:43:38
	System	19 Sep 2020 18:43:38

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:43:19', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ee8c2b09-5d1d-4d1c-9c9c-a64aaace2cb2' User entered 'None (0)'	System	19 Sep 2020 18:43:38
	System	19 Sep 2020 18:43:38

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:43:22', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ee8c2b09-5d1d-4d1c-9c9c-a64aaace2cb2' User entered 'None (0)'	System	19 Sep 2020 18:43:38
	System	19 Sep 2020 18:43:38

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:43:27', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ee8c2b09-5d1d-4d1c-9c9c-a64aaace2cb2' User entered 'None (0)'	System	19 Sep 2020 18:43:38
	System	19 Sep 2020 18:43:38

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:43:32', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ee8c2b09-5d1d-4d1c-9c9c-a64aaace2cb2' User entered 'No (N)'	System	19 Sep 2020 18:43:38
	System	19 Sep 2020 18:43:38

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-19T14:43:35', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ee8c2b09-5d1d-4d1c-9c9c-a64aaace2cb2' User entered '19 Sep 2020 14:43'	System	19 Sep 2020 18:43:38
	System	19 Sep 2020 18:43:38

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 14:27:22



**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 6'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:15:05', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f734e326-508a-4af1-9a62-fb8503b9884b' User entered 'None (0)'	System	20 Sep 2020 23:15:46
	System	20 Sep 2020 23:15:46

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:15:09', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f734e326-508a-4af1-9a62-fb8503b9884b' User entered 'None (0)'	System	20 Sep 2020 23:15:46
	System	20 Sep 2020 23:15:46

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:15:18', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f734e326-508a-4af1-9a62-fb8503b9884b' User entered 'None (0)'	System	20 Sep 2020 23:15:46
	System	20 Sep 2020 23:15:46

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:15:23', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f734e326-508a-4af1-9a62-fb8503b9884b' User entered 'None (0)'	System	20 Sep 2020 23:15:46
	System	20 Sep 2020 23:15:46

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:15:26', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f734e326-508a-4af1-9a62-fb8503b9884b' User entered 'None (0)'	System	20 Sep 2020 23:15:46
	System	20 Sep 2020 23:15:46

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:15:30', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f734e326-508a-4af1-9a62-fb8503b9884b' User entered 'None (0)'	System	20 Sep 2020 23:15:46
	System	20 Sep 2020 23:15:46



US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:15:41', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f734e326-508a-4af1-9a62-fb8503b9884b' User entered 'No (N)'	System	20 Sep 2020 23:15:46
	System	20 Sep 2020 23:15:46

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-20T19:15:44', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f734e326-508a-4af1-9a62-fb8503b9884b' User entered '20 Sep 2020 19:15'	System	20 Sep 2020 23:15:46
	System	20 Sep 2020 23:15:46

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 7'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:02:54', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'af018dac-7432-4f64-a03b-da036d437cc9' User entered 'None (0)'	System	21 Sep 2020 16:18:06
	System	21 Sep 2020 16:18:06

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:17:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:03:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'af018dac-7432-4f64-a03b-da036d437cc9' User entered 'None (0)'	System	21 Sep 2020 16:18:06
	System	21 Sep 2020 16:18:06

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:03:05', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'af018dac-7432-4f64-a03b-da036d437cc9' User entered 'None (0)'	System	21 Sep 2020 16:18:06
	System	21 Sep 2020 16:18:06



US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:03:08', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'af018dac-7432-4f64-a03b-da036d437cc9' User entered 'None (0)'	System	21 Sep 2020 16:18:06
	System	21 Sep 2020 16:18:06

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:03:11', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'af018dac-7432-4f64-a03b-da036d437cc9' User entered 'None (0)'	System	21 Sep 2020 16:18:06
	System	21 Sep 2020 16:18:06

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:03:16', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'af018dac-7432-4f64-a03b-da036d437cc9' User entered 'None (0)'	System	21 Sep 2020 16:18:06
	System	21 Sep 2020 16:18:06

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:03:30', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'af018dac-7432-4f64-a03b-da036d437cc9' User entered 'No (N)'	System	21 Sep 2020 16:18:06
	System	21 Sep 2020 16:18:06

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-09-21T12:03:34', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'af018dac-7432-4f64-a03b-da036d437cc9' User entered '21 Sep 2020 12:03'	System	21 Sep 2020 16:18:06
	System	21 Sep 2020 16:18:06

**US3372348**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 14:27:22

US3372348

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 14:27:22

**US3372348**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Yes (Y)'	Alexandra Arango (b) (4)	05 Oct 2020 15:41:07



US3372348

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 11:44:47
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Phone visit completed within window per protocol' (Site from System).	Alexandra Arango (b) (4) (b) (4)	05 Oct 2020 15:41:18
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Oct 2020 15:41:07
User entered '21 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	05 Oct 2020 15:41:07

**US3372348**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	05 Oct 2020 15:41:07

US3372348

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered empty.	(b) (4) Alexandra Arango (b) (4)	05 Oct 2020 15:41:07

**US3372348**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:45:05
User entered 'Yes (Y)'	Alexandra Arango (b) (4)	05 Oct 2020 15:41:23

**US3372348**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'I'	System	05 Oct 2020 15:41:23

**US3372348**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	05 Oct 2020 15:41:43

US3372348

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 11:45:16
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Phone visit completed within window per protocol' (Site from System).	Alexandra Arango (b) (4) (b) (4)	05 Oct 2020 15:41:47
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Oct 2020 15:41:43
User entered '28 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	05 Oct 2020 15:41:43

**US3372348**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	05 Oct 2020 15:41:43



US3372348

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered empty.	Alexandra Arango (b) (4)	05 Oct 2020 15:41:43

**US3372348**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:45:05
User entered 'Yes (Y)'	Alexandra Arango (b) (4)	05 Oct 2020 15:41:53

**US3372348**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'I'	System	05 Oct 2020 15:41:53

**US3372348**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	05 Oct 2020 16:05:39

US3372348

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 11:45:33
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Phone visit completed within window per protocol' (Site from System).	Alexandra Arango (b) (4) (b) (4)	05 Oct 2020 16:05:47
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Oct 2020 16:05:39
User entered '5 Oct 2020'	Alexandra Arango (b) (4) (b) (4)	05 Oct 2020 16:05:39

**US3372348**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4) (b) (4)	05 Oct 2020 16:05:39

US3372348

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered empty.	Alexandra Arango (b) (4)	05 Oct 2020 16:05:39

**US3372348**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:45:05
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	05 Oct 2020 16:05:53



**US3372348**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:14:59
User entered 'I'	System	05 Oct 2020 16:05:53

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:36:51

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:36:51

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:36:51

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'VISIT2'	System	13 Oct 2020 14:36:51

US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4)	14 Oct 2020 20:34:57
	(b) (4)	

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 20:34:57

US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '13 Oct 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:34:57



**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '09:10'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:34:57

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered '13 Oct 2020 09:10'	System	14 Oct 2020 20:34:57

US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '36.7' C	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 20:34:57

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:34:57

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered empty.	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 20:34:57

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '79'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:34:57

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'bpm'	System	14 Oct 2020 20:34:57

US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:34:57



US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'breaths/min'	System	14 Oct 2020 20:34:57

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '156'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:34:57

US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'mmHg'	System	14 Oct 2020 20:34:57

US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '80'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:34:57

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'mmHg'	System	14 Oct 2020 20:34:57

US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:35:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 20:35:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '13 Oct 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:35:17



**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '10:46'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:35:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered '13 Oct 2020 10:46'	System	14 Oct 2020 20:35:17

US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '36' C	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 20:35:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 20:35:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:35:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '82'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:35:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'bpm'	System	14 Oct 2020 20:35:17

US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:35:17



US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'breaths/min'	System	14 Oct 2020 20:35:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '158'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:35:17

US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'mmHg'	System	14 Oct 2020 20:35:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '84'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:35:17

US3372348

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'mmHg'	System	14 Oct 2020 20:35:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:17:58**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 20:35:24

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:17:58**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered empty.	Peter Jacob (b) (4)	14 Oct 2020 20:35:24

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:37:17



**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:37:17

US3372348

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:37:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:37:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '10:12'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:37:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered '13 Oct 2020 10:12'	System	13 Oct 2020 14:37:17

US3372348

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User closed query 'Per CDM :Re-query: Response provided as 'Correct' However, no AE is entered. Please review and consider to update or else provide clarification. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:51:11
Query 'Per CDM :Re-query: Response provided as 'Correct' However, no AE is entered. Please review and consider to update or else provide clarification. Thank you. ' answered with 'no AE required, subject bruised his arm and was unable to receive treatment on left arm.' (Site from DM).	Peter Jacob (b) (4) (b) (4)	17 Nov 2020 21:20:27
User opened query 'Per CDM :Re-query: Response provided as 'Correct' However, no AE is entered. Please review and consider to update or else provide clarification. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 12:42:01
User closed query 'Per CDM: Please confirm if "injury" noted is considered an AE and report if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 12:42:01
Query 'Per CDM: Please confirm if "injury" noted is considered an AE and report if necessary. Thank you' answered with 'correct' (Site from DM).	Peter Jacob (b) (4) (b) (4)	13 Nov 2020 20:28:40
User opened query 'Per CDM: Please confirm if "injury" noted is considered an AE and report if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:31:50
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 19:30:09
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'due to injury patient could not receive treatment in the same arm as first dose' (Site from System).	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:37:17
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	13 Oct 2020 14:37:17
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	13 Oct 2020 14:37:17

US3372348

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'ONCE'	System	13 Oct 2020 14:37:17



US3372348

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 20:37:33

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '13 Oct 2020'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 20:37:33

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered '09:40'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:37:33

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered '13 Oct 2020 09:40'	System	14 Oct 2020 20:37:33

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 17:17:58**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:27:24
User entered '13 Oct 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:37:45

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:37:45

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:27:24
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 20:37:45



**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:27:24
User entered '09:38'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:37:45

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered '13 Oct 2020 09:38'	System	14 Oct 2020 20:37:45

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:37:45

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:27:24
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 20:37:45

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:17:58**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:27:24
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 20:37:45

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered empty.	System	14 Oct 2020 20:37:45

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:28:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:37:31

**US3372348**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'I'	System	13 Oct 2020 14:37:31



US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:04:59', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ccd0e5cc-6909-4448-8a87-5067da3a6c70' User entered 'Yes (Y)'	System	13 Oct 2020 15:05:42
	System	13 Oct 2020 15:05:42

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:05:13', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ccd0e5cc-6909-4448-8a87-5067da3a6c70' User entered '96.8'	System	13 Oct 2020 15:05:42
	System	13 Oct 2020 15:05:42

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:05:26', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ccd0e5cc-6909-4448-8a87-5067da3a6c70'	System	13 Oct 2020 15:05:42
User entered 'No (N)'	System	13 Oct 2020 15:05:42

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:05:38', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ccd0e5cc-6909-4448-8a87-5067da3a6c70' User entered '13 Oct 2020 11:05'	System	13 Oct 2020 15:05:42
	System	13 Oct 2020 15:05:42

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '13 Oct 2020 10:32'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '13 Oct 2020 13:02'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 14:37:17



US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:30:34', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '76891f05-b202-419a-bb05-b43e9cf170f7' User entered 'Yes (Y)'	System	14 Oct 2020 10:31:06
	System	14 Oct 2020 10:31:06

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:30:48', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '76891f05-b202-419a-bb05-b43e9cf170f7' User entered '97.7'	System	14 Oct 2020 10:31:06
	System	14 Oct 2020 10:31:06

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:30:57', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '76891f05-b202-419a-bb05-b43e9cf170f7'	System	14 Oct 2020 10:31:06
User entered 'No (N)'	System	14 Oct 2020 10:31:06

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:31:03', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '76891f05-b202-419a-bb05-b43e9cf170f7' User entered '14 Oct 2020 06:31'	System	14 Oct 2020 10:31:06
	System	14 Oct 2020 10:31:06

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '13 Oct 2020 13:57'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 2'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:00:45', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '6a2a00a9-4006-4d0c-9aeb-671fa392996b' User entered 'Yes (Y)'	System	15 Oct 2020 12:01:16
	System	15 Oct 2020 12:01:16



US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:00:58', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '6a2a00a9-4006-4d0c-9aeb-671fa392996b' User entered '97.7'	System	15 Oct 2020 12:01:16
	System	15 Oct 2020 12:01:16

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:01:04', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '6a2a00a9-4006-4d0c-9aeb-671fa392996b' User entered 'No (N)'	System	15 Oct 2020 12:01:16
	System	15 Oct 2020 12:01:16

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:01:10', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '6a2a00a9-4006-4d0c-9aeb-671fa392996b' User entered '15 Oct 2020 08:01'	System	15 Oct 2020 12:01:16
	System	15 Oct 2020 12:01:16

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 3'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:34:46', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '81aa703f-7c55-4126-ad6f-fc5bbfb129e2' User entered 'Yes (Y)'	System	16 Oct 2020 12:35:10
	System	16 Oct 2020 12:35:10

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:34:55', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '81aa703f-7c55-4126-ad6f-fc5bbfb129e2' User entered '97.7'	System	16 Oct 2020 12:35:10
	System	16 Oct 2020 12:35:10



US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:35:02', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '81aa703f-7c55-4126-ad6f-fc5bbfb129e2'	System	16 Oct 2020 12:35:10
User entered 'No (N)'	System	16 Oct 2020 12:35:10

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:35:07', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '81aa703f-7c55-4126-ad6f-fc5bbfb129e2' User entered '16 Oct 2020 08:35'	System	16 Oct 2020 12:35:10
	System	16 Oct 2020 12:35:10

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 4'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:24:29', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '943f4b7f-2ddd-40d9-a9b7-e3ae192a77bc' User entered 'Yes (Y)'	System	17 Oct 2020 10:24:51
	System	17 Oct 2020 10:24:51

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:24:37', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '943f4b7f-2ddd-40d9-a9b7-e3ae192a77bc' User entered '97.7'	System	17 Oct 2020 10:24:51
	System	17 Oct 2020 10:24:51

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:24:43', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '943f4b7f-2ddd-40d9-a9b7-e3ae192a77bc'	System	17 Oct 2020 10:24:51
User entered 'No (N)'	System	17 Oct 2020 10:24:51



**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:24:48', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '943f4b7f-2ddd-40d9-a9b7-e3ae192a77bc' User entered '17 Oct 2020 06:24'	System	17 Oct 2020 10:24:51
	System	17 Oct 2020 10:24:51

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 5'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:36:27', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '485b6359-ddf4-4090-8dd7-e0e9ca72bfcd' User entered 'Yes (Y)'	System	18 Oct 2020 11:36:59
	System	18 Oct 2020 11:36:59

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:36:38', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '485b6359-ddf4-4090-8dd7-e0e9ca72bfcd' User entered '97.7'	System	18 Oct 2020 11:36:59
	System	18 Oct 2020 11:36:59

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:36:47', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '485b6359-ddf4-4090-8dd7-e0e9ca72bfcd' User entered 'No (N)'	System	18 Oct 2020 11:36:59
	System	18 Oct 2020 11:36:59

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:36:54', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '485b6359-ddf4-4090-8dd7-e0e9ca72bfcd' User entered '18 Oct 2020 07:36'	System	18 Oct 2020 11:36:59
	System	18 Oct 2020 11:36:59



**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 6'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:13:33', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '2692351d-bca6-4355-85ec-e75fe49eab80' User entered 'Yes (Y)'	System	19 Oct 2020 12:14:00
	System	19 Oct 2020 12:14:00

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:13:44', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '2692351d-bca6-4355-85ec-e75fe49eab80' User entered '97.5'	System	19 Oct 2020 12:14:00
	System	19 Oct 2020 12:14:00

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:13:50', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '2692351d-bca6-4355-85ec-e75fe49eab80' User entered 'No (N)'	System	19 Oct 2020 12:14:00
	System	19 Oct 2020 12:14:00

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:13:52', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '2692351d-bca6-4355-85ec-e75fe49eab80' User entered '19 Oct 2020 08:13'	System	19 Oct 2020 12:14:00
	System	19 Oct 2020 12:14:00

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 14:37:17



**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 7'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:17:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:04:25', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'a4e49516-6993-4d33-b598-754a0664f90e' User entered 'Yes (Y)'	System	20 Oct 2020 11:04:45
	System	20 Oct 2020 11:04:45

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:04:33', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'a4e49516-6993-4d33-b598-754a0664f90e' User entered '97.6'	System	20 Oct 2020 11:04:45
	System	20 Oct 2020 11:04:45

US3372348

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:04:40', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'a4e49516-6993-4d33-b598-754a0664f90e' User entered 'No (N)'	System	20 Oct 2020 11:04:45
	System	20 Oct 2020 11:04:45

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:04:43', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'a4e49516-6993-4d33-b598-754a0664f90e' User entered '20 Oct 2020 07:04'	System	20 Oct 2020 11:04:45
	System	20 Oct 2020 11:04:45

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 14:37:17



US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:05:49', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f96c1397-a3ed-4f18-b272-c6b5b1394fc4'	System	13 Oct 2020 15:06:20
User entered 'None (1)'	System	13 Oct 2020 15:06:20

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:05:54', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f96c1397-a3ed-4f18-b272-c6b5b1394fc4' User entered 'No (N)'	System	13 Oct 2020 15:06:20
	System	13 Oct 2020 15:06:20

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:05:58', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f96c1397-a3ed-4f18-b272-c6b5b1394fc4' User entered 'No (N)'	System	13 Oct 2020 15:06:20
	System	13 Oct 2020 15:06:20

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:06:05', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f96c1397-a3ed-4f18-b272-c6b5b1394fc4'	System	13 Oct 2020 15:06:20
User entered 'None (1)'	System	13 Oct 2020 15:06:20

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:06:10', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f96c1397-a3ed-4f18-b272-c6b5b1394fc4' User entered '13 Oct 2020 11:06'	System	13 Oct 2020 15:06:20
	System	13 Oct 2020 15:06:20

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '13 Oct 2020 10:32'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '13 Oct 2020 13:02'	System	13 Oct 2020 14:37:17



US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:31:30', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c2bc6542-969d-48e0-8936-160da15598a6'	System	14 Oct 2020 10:31:59
User entered 'None (1)'	System	14 Oct 2020 10:31:59

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:31:34', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c2bc6542-969d-48e0-8936-160da15598a6' User entered 'No (N)'	System	14 Oct 2020 10:31:59
	System	14 Oct 2020 10:31:59

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:31:40', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c2bc6542-969d-48e0-8936-160da15598a6' User entered 'No (N)'	System	14 Oct 2020 10:31:59
	System	14 Oct 2020 10:31:59

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:31:46', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c2bc6542-969d-48e0-8936-160da15598a6'	System	14 Oct 2020 10:31:59
User entered 'None (1)'	System	14 Oct 2020 10:31:59

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:31:53', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'c2bc6542-969d-48e0-8936-160da15598a6' User entered '14 Oct 2020 06:31'	System	14 Oct 2020 10:31:59
	System	14 Oct 2020 10:31:59

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '13 Oct 2020 13:57'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 14:37:17



US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 2'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:01:23', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '864bdc1e-55dd-4b7b-b15b-465ed98b1eb3'	System	15 Oct 2020 12:02:02
User entered 'None (1)'	System	15 Oct 2020 12:02:02

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:01:28', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '864bdc1e-55dd-4b7b-b15b-465ed98b1eb3'	System	15 Oct 2020 12:02:02
User entered 'No (N)'	System	15 Oct 2020 12:02:02

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:01:38', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '864bdc1e-55dd-4b7b-b15b-465ed98b1eb3'	System	15 Oct 2020 12:02:02
User entered 'No (N)'	System	15 Oct 2020 12:02:02

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:01:54', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '864bdc1e-55dd-4b7b-b15b-465ed98b1eb3'	System	15 Oct 2020 12:02:02
User entered 'None (1)'	System	15 Oct 2020 12:02:02

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:01:57', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '864bdc1e-55dd-4b7b-b15b-465ed98b1eb3'	System	15 Oct 2020 12:02:02
User entered '15 Oct 2020 08:01'	System	15 Oct 2020 12:02:02

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 14:37:17



**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 3'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:35:22', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '692b835b-18c3-4891-8b71-f5ce6098cb54' User entered 'None (1)'	System	16 Oct 2020 12:35:39
	System	16 Oct 2020 12:35:39

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:35:28', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '692b835b-18c3-4891-8b71-f5ce6098cb54' User entered 'No (N)'	System	16 Oct 2020 12:35:39
	System	16 Oct 2020 12:35:39

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:35:31', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '692b835b-18c3-4891-8b71-f5ce6098cb54' User entered 'No (N)'	System	16 Oct 2020 12:35:39
	System	16 Oct 2020 12:35:39

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:35:34', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '692b835b-18c3-4891-8b71-f5ce6098cb54'	System	16 Oct 2020 12:35:39
User entered 'None (1)'	System	16 Oct 2020 12:35:39

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:35:37', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '692b835b-18c3-4891-8b71-f5ce6098cb54' User entered '16 Oct 2020 08:35'	System	16 Oct 2020 12:35:39
	System	16 Oct 2020 12:35:39

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 14:37:17



US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 4'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:24:56', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '7a6e4398-3f11-43f0-9976-ac7720c667d7'	System	17 Oct 2020 10:25:11
User entered 'None (1)'	System	17 Oct 2020 10:25:11

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:24:59', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '7a6e4398-3f11-43f0-9976-ac7720c667d7'	System	17 Oct 2020 10:25:11
User entered 'No (N)'	System	17 Oct 2020 10:25:11

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:25:02', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '7a6e4398-3f11-43f0-9976-ac7720c667d7'	System	17 Oct 2020 10:25:11
User entered 'No (N)'	System	17 Oct 2020 10:25:11

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:25:05', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '7a6e4398-3f11-43f0-9976-ac7720c667d7'	System	17 Oct 2020 10:25:11
User entered 'None (1)'	System	17 Oct 2020 10:25:11

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:25:09', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '7a6e4398-3f11-43f0-9976-ac7720c667d7' User entered '17 Oct 2020 06:25'	System	17 Oct 2020 10:25:11
	System	17 Oct 2020 10:25:11

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 14:37:17



US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 5'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:37:02', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f018e847-b9dd-4a2d-87d3-a58bdcddf138' User entered 'None (1)'	System	18 Oct 2020 11:37:27
	System	18 Oct 2020 11:37:27

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:37:06', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f018e847-b9dd-4a2d-87d3-a58bdcddf138' User entered 'No (N)'	System	18 Oct 2020 11:37:27
	System	18 Oct 2020 11:37:27

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:37:10', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f018e847-b9dd-4a2d-87d3-a58bdcddf138' User entered 'No (N)'	System	18 Oct 2020 11:37:27
	System	18 Oct 2020 11:37:27

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:37:17', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f018e847-b9dd-4a2d-87d3-a58bdcddf138' User entered 'None (1)'	System	18 Oct 2020 11:37:27
	System	18 Oct 2020 11:37:27

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:37:24', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f018e847-b9dd-4a2d-87d3-a58bdcddf138' User entered '18 Oct 2020 07:37'	System	18 Oct 2020 11:37:27
	System	18 Oct 2020 11:37:27

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 14:37:17



US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 6'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:14:06', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ec99a767-bc8a-4e97-b88c-0e32e1a6cd84'	System	19 Oct 2020 12:14:27
User entered 'None (1)'	System	19 Oct 2020 12:14:27

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:14:09', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ec99a767-bc8a-4e97-b88c-0e32e1a6cd84' User entered 'No (N)'	System	19 Oct 2020 12:14:27
	System	19 Oct 2020 12:14:27

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:14:12', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ec99a767-bc8a-4e97-b88c-0e32e1a6cd84' User entered 'No (N)'	System	19 Oct 2020 12:14:27
	System	19 Oct 2020 12:14:27

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:14:15', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ec99a767-bc8a-4e97-b88c-0e32e1a6cd84'	System	19 Oct 2020 12:14:27
User entered 'None (1)'	System	19 Oct 2020 12:14:27

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:14:18', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ec99a767-bc8a-4e97-b88c-0e32e1a6cd84' User entered '19 Oct 2020 08:14'	System	19 Oct 2020 12:14:27
	System	19 Oct 2020 12:14:27

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 14:37:17



US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 7'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:04:56', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '18ded2cf-c520-4743-b165-1102533b482a' User entered 'None (1)'	System	20 Oct 2020 11:05:14
	System	20 Oct 2020 11:05:14

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:17:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:05:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '18ded2cf-c520-4743-b165-1102533b482a' User entered 'No (N)'	System	20 Oct 2020 11:05:14
	System	20 Oct 2020 11:05:14

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:05:03', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '18ded2cf-c520-4743-b165-1102533b482a' User entered 'No (N)'	System	20 Oct 2020 11:05:14
	System	20 Oct 2020 11:05:14

US3372348

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:05:07', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '18ded2cf-c520-4743-b165-1102533b482a' User entered 'None (1)'	System	20 Oct 2020 11:05:14
	System	20 Oct 2020 11:05:14

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:05:11', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '18ded2cf-c520-4743-b165-1102533b482a' User entered '20 Oct 2020 07:05'	System	20 Oct 2020 11:05:14
	System	20 Oct 2020 11:05:14

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 14:37:17



US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:06:19', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'bebfcdba-6f83-4c58-bcf9-7e6f550f745e' User entered 'None (0)'	System	13 Oct 2020 15:06:54
	System	13 Oct 2020 15:06:54

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:06:24', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'bebfcdba-6f83-4c58-bcf9-7e6f550f745e' User entered 'None (0)'	System	13 Oct 2020 15:06:54
	System	13 Oct 2020 15:06:54

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:06:28', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'bebfcdba-6f83-4c58-bcf9-7e6f550f745e' User entered 'None (0)'	System	13 Oct 2020 15:06:54
	System	13 Oct 2020 15:06:54

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:06:31', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'bebfcdba-6f83-4c58-bcf9-7e6f550f745e' User entered 'None (0)'	System	13 Oct 2020 15:06:54
	System	13 Oct 2020 15:06:54

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:06:34', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'bebfcdba-6f83-4c58-bcf9-7e6f550f745e' User entered 'None (0)'	System	13 Oct 2020 15:06:54
	System	13 Oct 2020 15:06:54

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:06:38', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'bebfcdba-6f83-4c58-bcf9-7e6f550f745e' User entered 'None (0)'	System	13 Oct 2020 15:06:54
	System	13 Oct 2020 15:06:54

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:06:43', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'bebfcdba-6f83-4c58-bcf9-7e6f550f745e' User entered 'No (N)'	System	13 Oct 2020 15:06:54
	System	13 Oct 2020 15:06:54



**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-13T11:06:47', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'bebfcdba-6f83-4c58-bcf9-7e6f550f745e' User entered '13 Oct 2020 11:06'	System	13 Oct 2020 15:06:54
	System	13 Oct 2020 15:06:54

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '13 Oct 2020 10:32'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '13 Oct 2020 13:02'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:32:03', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b31c93ba-3e28-435d-9e27-d3e8e3de4c5e' User entered 'None (0)'	System	14 Oct 2020 10:32:45
	System	14 Oct 2020 10:32:45

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:32:07', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b31c93ba-3e28-435d-9e27-d3e8e3de4c5e' User entered 'None (0)'	System	14 Oct 2020 10:32:45
	System	14 Oct 2020 10:32:45

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:32:13', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b31c93ba-3e28-435d-9e27-d3e8e3de4c5e' User entered 'None (0)'	System	14 Oct 2020 10:32:45
	System	14 Oct 2020 10:32:45

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:32:16', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b31c93ba-3e28-435d-9e27-d3e8e3de4c5e' User entered 'None (0)'	System	14 Oct 2020 10:32:45
	System	14 Oct 2020 10:32:45



US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:32:24', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b31c93ba-3e28-435d-9e27-d3e8e3de4c5e' User entered 'None (0)'	System	14 Oct 2020 10:32:45
	System	14 Oct 2020 10:32:45

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:32:29', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b31c93ba-3e28-435d-9e27-d3e8e3de4c5e' User entered 'None (0)'	System	14 Oct 2020 10:32:45
	System	14 Oct 2020 10:32:45

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:32:36', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b31c93ba-3e28-435d-9e27-d3e8e3de4c5e' User entered 'No (N)'	System	14 Oct 2020 10:32:45
	System	14 Oct 2020 10:32:45

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-14T06:32:40', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'b31c93ba-3e28-435d-9e27-d3e8e3de4c5e' User entered '14 Oct 2020 06:32'	System	14 Oct 2020 10:32:45
	System	14 Oct 2020 10:32:45

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '13 Oct 2020 13:57'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 2'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:02:07', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '4b6afdc6-19ab-4dec-8225-92b4c782c1e1' User entered 'None (0)'	System	15 Oct 2020 12:02:41
	System	15 Oct 2020 12:02:41



US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:02:12', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '4b6afdc6-19ab-4dec-8225-92b4c782c1e1' User entered 'None (0)'	System	15 Oct 2020 12:02:41
	System	15 Oct 2020 12:02:41

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:02:17', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '4b6afdc6-19ab-4dec-8225-92b4c782c1e1' User entered 'None (0)'	System	15 Oct 2020 12:02:41
	System	15 Oct 2020 12:02:41

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:02:22', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '4b6afdc6-19ab-4dec-8225-92b4c782c1e1' User entered 'None (0)'	System	15 Oct 2020 12:02:41
	System	15 Oct 2020 12:02:41

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:02:26', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '4b6afdc6-19ab-4dec-8225-92b4c782c1e1' User entered 'None (0)'	System	15 Oct 2020 12:02:41
	System	15 Oct 2020 12:02:41

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:02:29', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '4b6afdc6-19ab-4dec-8225-92b4c782c1e1' User entered 'None (0)'	System	15 Oct 2020 12:02:41
	System	15 Oct 2020 12:02:41

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:02:34', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '4b6afdc6-19ab-4dec-8225-92b4c782c1e1' User entered 'No (N)'	System	15 Oct 2020 12:02:41
	System	15 Oct 2020 12:02:41

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-15T08:02:38', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '4b6afdc6-19ab-4dec-8225-92b4c782c1e1' User entered '15 Oct 2020 08:02'	System	15 Oct 2020 12:02:41
	System	15 Oct 2020 12:02:41

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 14:37:17



**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 3'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:35:44', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '14d5b666-2b2c-415b-88d5-d983470ea691' User entered 'None (0)'	System	16 Oct 2020 12:36:12
	System	16 Oct 2020 12:36:12

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:35:46', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '14d5b666-2b2c-415b-88d5-d983470ea691' User entered 'None (0)'	System	16 Oct 2020 12:36:12
	System	16 Oct 2020 12:36:12

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:35:49', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '14d5b666-2b2c-415b-88d5-d983470ea691' User entered 'None (0)'	System	16 Oct 2020 12:36:12
	System	16 Oct 2020 12:36:12

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:35:51', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '14d5b666-2b2c-415b-88d5-d983470ea691' User entered 'None (0)'	System	16 Oct 2020 12:36:12
	System	16 Oct 2020 12:36:12

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:35:57', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '14d5b666-2b2c-415b-88d5-d983470ea691' User entered 'None (0)'	System	16 Oct 2020 12:36:12
	System	16 Oct 2020 12:36:12

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:36:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '14d5b666-2b2c-415b-88d5-d983470ea691' User entered 'None (0)'	System	16 Oct 2020 12:36:12
	System	16 Oct 2020 12:36:12



US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:36:04', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '14d5b666-2b2c-415b-88d5-d983470ea691' User entered 'No (N)'	System	16 Oct 2020 12:36:12
	System	16 Oct 2020 12:36:12

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-16T08:36:10', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '14d5b666-2b2c-415b-88d5-d983470ea691' User entered '16 Oct 2020 08:36'	System	16 Oct 2020 12:36:12
	System	16 Oct 2020 12:36:12

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 4'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:25:15', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3bf7aef2-a2af-4a9e-a810-ead628304c8e' User entered 'None (0)'	System	17 Oct 2020 10:25:47
	System	17 Oct 2020 10:25:47

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:25:18', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3bf7aef2-a2af-4a9e-a810-ead628304c8e' User entered 'None (0)'	System	17 Oct 2020 10:25:47
	System	17 Oct 2020 10:25:47

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:25:24', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3bf7aef2-a2af-4a9e-a810-ead628304c8e' User entered 'None (0)'	System	17 Oct 2020 10:25:47
	System	17 Oct 2020 10:25:47



US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:25:27', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3bf7aef2-a2af-4a9e-a810-ead628304c8e' User entered 'None (0)'	System	17 Oct 2020 10:25:47
	System	17 Oct 2020 10:25:47

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:25:29', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3bf7aef2-a2af-4a9e-a810-ead628304c8e' User entered 'None (0)'	System	17 Oct 2020 10:25:47
	System	17 Oct 2020 10:25:47

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:25:34', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3bf7aef2-a2af-4a9e-a810-ead628304c8e' User entered 'None (0)'	System	17 Oct 2020 10:25:47
	System	17 Oct 2020 10:25:47

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:25:38', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3bf7aef2-a2af-4a9e-a810-ead628304c8e' User entered 'No (N)'	System	17 Oct 2020 10:25:47
	System	17 Oct 2020 10:25:47

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-17T06:25:43', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3bf7aef2-a2af-4a9e-a810-ead628304c8e' User entered '17 Oct 2020 06:25'	System	17 Oct 2020 10:25:47
	System	17 Oct 2020 10:25:47

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 5'	System	13 Oct 2020 14:37:17



US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:37:40', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1fe8ef7a-1e63-4ad1-a774-ef1ecef20ea'	System	18 Oct 2020 11:38:12
User entered 'None (0)'	System	18 Oct 2020 11:38:12

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:37:43', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1fe8ef7a-1e63-4ad1-a774-ef1ecef20ea' User entered 'None (0)'	System	18 Oct 2020 11:38:12
	System	18 Oct 2020 11:38:12

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:37:48', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1fe8ef7a-1e63-4ad1-a774-ef1ecef20ea'	System	18 Oct 2020 11:38:12
User entered 'None (0)'	System	18 Oct 2020 11:38:12

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:37:52', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1fe8ef7a-1e63-4ad1-a774-ef1ecef20ea' User entered 'None (0)'	System	18 Oct 2020 11:38:12
	System	18 Oct 2020 11:38:12

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:37:55', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1fe8ef7a-1e63-4ad1-a774-ef1ecef20ea'	System	18 Oct 2020 11:38:12
User entered 'None (0)'	System	18 Oct 2020 11:38:12

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:38:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1fe8ef7a-1e63-4ad1-a774-ef1ecef20ea'	System	18 Oct 2020 11:38:12
User entered 'None (0)'	System	18 Oct 2020 11:38:12

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:38:05', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1fe8ef7a-1e63-4ad1-a774-ef1ecef20ea'	System	18 Oct 2020 11:38:12
User entered 'No (N)'	System	18 Oct 2020 11:38:12

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-18T07:38:10', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '1fe8ef7a-1e63-4ad1-a774-ef1ecef20ea' User entered '18 Oct 2020 07:38'	System	18 Oct 2020 11:38:12
	System	18 Oct 2020 11:38:12



**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 6'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:14:25', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8ad34d01-1220-455f-8bde-30cd68f4467d' User entered 'None (0)'	System	19 Oct 2020 12:14:55
	System	19 Oct 2020 12:14:55

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:14:29', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8ad34d01-1220-455f-8bde-30cd68f4467d' User entered 'None (0)'	System	19 Oct 2020 12:14:55
	System	19 Oct 2020 12:14:55

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:14:31', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8ad34d01-1220-455f-8bde-30cd68f4467d' User entered 'None (0)'	System	19 Oct 2020 12:14:55
	System	19 Oct 2020 12:14:55

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:14:34', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8ad34d01-1220-455f-8bde-30cd68f4467d' User entered 'None (0)'	System	19 Oct 2020 12:14:55
	System	19 Oct 2020 12:14:55

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:17:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:14:37', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8ad34d01-1220-455f-8bde-30cd68f4467d' User entered 'None (0)'	System	19 Oct 2020 12:14:55
	System	19 Oct 2020 12:14:55



**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:14:39', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8ad34d01-1220-455f-8bde-30cd68f4467d' User entered 'None (0)'	System	19 Oct 2020 12:14:55
	System	19 Oct 2020 12:14:55

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:14:47', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8ad34d01-1220-455f-8bde-30cd68f4467d' User entered 'No (N)'	System	19 Oct 2020 12:14:55
	System	19 Oct 2020 12:14:55

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-19T08:14:50', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8ad34d01-1220-455f-8bde-30cd68f4467d' User entered '19 Oct 2020 08:14'	System	19 Oct 2020 12:14:55
	System	19 Oct 2020 12:14:55

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	13 Oct 2020 14:37:17
User entered 'Day 7'	System	13 Oct 2020 14:37:17

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:17:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:05:18', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3f85743b-0201-4594-b34d-ca2184789898' User entered 'None (0)'	System	20 Oct 2020 11:05:56
	System	20 Oct 2020 11:05:56

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:17:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:05:24', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3f85743b-0201-4594-b34d-ca2184789898' User entered 'None (0)'	System	20 Oct 2020 11:05:56
	System	20 Oct 2020 11:05:56



**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:05:30', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3f85743b-0201-4594-b34d-ca2184789898' User entered 'None (0)'	System	20 Oct 2020 11:05:56
	System	20 Oct 2020 11:05:56

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:05:33', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3f85743b-0201-4594-b34d-ca2184789898' User entered 'None (0)'	System	20 Oct 2020 11:05:56
	System	20 Oct 2020 11:05:56

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:05:39', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3f85743b-0201-4594-b34d-ca2184789898' User entered 'None (0)'	System	20 Oct 2020 11:05:56
	System	20 Oct 2020 11:05:56

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:17:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:05:43', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3f85743b-0201-4594-b34d-ca2184789898' User entered 'None (0)'	System	20 Oct 2020 11:05:56
	System	20 Oct 2020 11:05:56

US3372348

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:17:58

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 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:05:46', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3f85743b-0201-4594-b34d-ca2184789898' User entered 'No (N)'	System	20 Oct 2020 11:05:56
	System	20 Oct 2020 11:05:56

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-10-20T07:05:51', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3f85743b-0201-4594-b34d-ca2184789898' User entered '20 Oct 2020 07:05'	System	20 Oct 2020 11:05:56
	System	20 Oct 2020 11:05:56

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 14:37:17

**US3372348**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:17:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 14:37:17



**US3372348**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Oct 2020 14:08:05

**US3372348**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered '20 Oct 2020'	(b) (4) Danielle Theodore (b) (4)	27 Oct 2020 14:08:05

**US3372348**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	27 Oct 2020 14:08:05

US3372348

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Oct 2020 14:08:05

US3372348

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:45:05
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	27 Oct 2020 14:08:12

**US3372348**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'I'	System	27 Oct 2020 14:08:12

**US3372348**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Oct 2020 14:08:26

**US3372348**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered '27 Oct 2020'	(b) (4) Danielle Theodore (b) (4)	27 Oct 2020 14:08:26
	(b) (4)	



**US3372348**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	27 Oct 2020 14:08:26

US3372348

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	27 Oct 2020 14:08:26

**US3372348**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:45:05
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	27 Oct 2020 14:08:32

**US3372348**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'I'	System	27 Oct 2020 14:08:32

**US3372348**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	03 Nov 2020 17:29:20

**US3372348**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered '3 Nov 2020'	(b) (4) Alexandra Arango (b) (4)	03 Nov 2020 17:29:20

**US3372348**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	03 Nov 2020 17:29:20

**US3372348**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered empty.	(b) (4) Alexandra Arango (b) (4)	03 Nov 2020 17:29:20
	(b) (4)	



**US3372348**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:45:05
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	03 Nov 2020 17:29:23

**US3372348**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'I'	System	03 Nov 2020 17:29:23

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:54:56

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:54:56

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:54:56

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'VISIT3'	System	09 Nov 2020 20:54:56

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:02

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:02



**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:02

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered empty.	System	09 Nov 2020 20:55:02

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:02

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:02

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:02

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:02

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered empty.	System	09 Nov 2020 20:55:02

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:02



**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered empty.	System	09 Nov 2020 20:55:02

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:02

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered empty.	System	09 Nov 2020 20:55:02

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:02

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered empty.	System	09 Nov 2020 20:55:02

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:17:58**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:08



**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:17:58**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:08

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:21

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:21

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered '09:19'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:55:21

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered '9 Nov 2020 09:19'	System	09 Nov 2020 20:55:21

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:08:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:56:23

**US3372348**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'I'	System	09 Nov 2020 20:56:23

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered 'Day 64'	System	15 Sep 2020 14:27:22



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-11-16T06:58:21', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '05aad884-77a6-46c9-9ea7-9046497413e8' User entered 'No (N)'	System	16 Nov 2020 11:58:55
	System	16 Nov 2020 11:58:55

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Have you been exposed to someone with 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)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-11-16T06:58:40', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '05aad884-77a6-46c9-9ea7-9046497413e8' User entered 'No (N)'	System	16 Nov 2020 11:58:55
	System	16 Nov 2020 11:58:55

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-11-16T06:58:51', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '05aad884-77a6-46c9-9ea7-9046497413e8' User entered '16 Nov 2020 06:58:51'	System	16 Nov 2020 11:58:55
	System	16 Nov 2020 11:58:55

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered '15 Nov 2020 00:01'	System	15 Sep 2020 14:27:22

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:30:52
Data entry locked.	System	15 Sep 2020 14:27:22
User entered '19 Nov 2020 23:59'	System	15 Sep 2020 14:27:22

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-11-21T09:16:18', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '71258e5c-4064-47b9-89d4-ddbae90225a4'	System	21 Nov 2020 14:16:49
User entered 'No (N)'	System	21 Nov 2020 14:16:49

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-11-21T09:16:35', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '71258e5c-4064-47b9-89d4-ddbae90225a4'	System	21 Nov 2020 14:16:49
User entered 'No (N)'	System	21 Nov 2020 14:16:49



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-11-21T09:16:46', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '71258e5c-4064-47b9-89d4-ddbae90225a4'	System	21 Nov 2020 14:16:49
User entered '21 Nov 2020 09:16:46'	System	21 Nov 2020 14:16:49

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-11-26T00:02:46', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'e57635c6-6618-4491-b32b-f608b57076db' User entered 'No (N)'	System	26 Nov 2020 05:03:09

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-11-26T00:02:56', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'e57635c6-6618-4491-b32b-f608b57076db' User entered 'No (N)'	System	26 Nov 2020 05:03:09

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-11-26T00:03:01', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'e57635c6-6618-4491-b32b-f608b57076db' User entered '26 Nov 2020 00:03:01'	System	26 Nov 2020 05:03:09
	System	26 Nov 2020 05:03:09

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 05:51:15



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-12-04T07:23:03', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '47f1160f-aa5e-4935-a598-be34c0eee343'	System	04 Dec 2020 12:23:31
User entered 'No (N)'	System	04 Dec 2020 12:23:31

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-12-04T07:23:18', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '47f1160f-aa5e-4935-a598-be34c0eee343'	System	04 Dec 2020 12:23:31
User entered 'No (N)'	System	04 Dec 2020 12:23:31

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-12-04T07:23:24', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '47f1160f-aa5e-4935-a598-be34c0eee343' User entered '04 Dec 2020 07:23:24'	System	04 Dec 2020 12:23:31
	System	04 Dec 2020 12:23:31

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 05:51:15



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-12-10T08:32:41', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f7996d50-0b81-4118-9141-aa986d9debb8' User entered 'No (N)'	System	10 Dec 2020 13:33:11
	System	10 Dec 2020 13:33:11

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-12-10T08:32:54', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f7996d50-0b81-4118-9141-aa986d9debb8' User entered 'No (N)'	System	10 Dec 2020 13:33:11

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-12-10T08:33:07', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f7996d50-0b81-4118-9141-aa986d9debb8' User entered '10 Dec 2020 08:33:07'	System	10 Dec 2020 13:33:11
	System	10 Dec 2020 13:33:11

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-12-17T07:46:01', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8f7d389f-efb0-4dd0-927e-1a35f4032182'	System	17 Dec 2020 12:46:24
User entered 'No (N)'	System	17 Dec 2020 12:46:24

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-12-17T07:46:11', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8f7d389f-efb0-4dd0-927e-1a35f4032182'	System	17 Dec 2020 12:46:24
User entered 'No (N)'	System	17 Dec 2020 12:46:24



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-12-17T07:46:18', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '8f7d389f-efb0-4dd0-927e-1a35f4032182' User entered '17 Dec 2020 07:46:18'	System	17 Dec 2020 12:46:24
	System	17 Dec 2020 12:46:24

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-12-24T08:46:15', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'bbc1a850-c687-4361-b001-d9345b01b94c'	System	24 Dec 2020 13:46:28
User entered 'No (N)'	System	24 Dec 2020 13:46:28

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-12-24T08:46:21', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'bbc1a850-c687-4361-b001-d9345b01b94c'	System	24 Dec 2020 13:46:28
User entered 'No (N)'	System	24 Dec 2020 13:46:28

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2020-12-24T08:46:26', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'bbc1a850-c687-4361-b001-d9345b01b94c' User entered '24 Dec 2020 08:46:26'	System	24 Dec 2020 13:46:28
	System	24 Dec 2020 13:46:28

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 05:51:15



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-01T12:03:25', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '5d735a8d-2194-44aa-8c95-a74bb19285b3' User entered 'No (N)'	System	01 Jan 2021 17:03:41
	System	01 Jan 2021 17:03:41

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-01T12:03:32', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '5d735a8d-2194-44aa-8c95-a74bb19285b3'	System	01 Jan 2021 17:03:41
User entered 'No (N)'	System	01 Jan 2021 17:03:41

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-01T12:03:39', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '5d735a8d-2194-44aa-8c95-a74bb19285b3' User entered '01 Jan 2021 12:03:39'	System	01 Jan 2021 17:03:41
	System	01 Jan 2021 17:03:41

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 05:51:15



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-07T00:02:36', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '9ab0cd36-e1c1-4115-bef5-d1de908d1eaa' User entered 'No (N)'	System	07 Jan 2021 05:03:08
	System	07 Jan 2021 05:03:08

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-07T00:02:48', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '9ab0cd36-e1c1-4115-bef5-d1de908d1eaa' User entered 'No (N)'	System	07 Jan 2021 05:03:08

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-07T00:02:59', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '9ab0cd36-e1c1-4115-bef5-d1de908d1eaa' User entered '07 Jan 2021 00:02:59'	System	07 Jan 2021 05:03:08
	System	07 Jan 2021 05:03:08

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-15T19:43:03', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'e7bb77c0-a835-41f1-81ea-f7e1d7ec5ba'	System	16 Jan 2021 00:43:20
User entered 'No (N)'	System	16 Jan 2021 00:43:20

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-15T19:43:09', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'e7bb77c0-a835-41f1-81ea-f7e1d7ec5ba'	System	16 Jan 2021 00:43:20
User entered 'No (N)'	System	16 Jan 2021 00:43:20



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-15T19:43:15', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'e7bb77c0-a835-41f1-81ea-f7e1d7ec5ba'	System	16 Jan 2021 00:43:20
User entered '15 Jan 2021 19:43:15'	System	16 Jan 2021 00:43:20

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-21T00:03:04', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'bb0f41c9-74ab-4a61-8a60-6ad28021defd' User entered 'No (N)'	System	21 Jan 2021 05:03:16
	System	21 Jan 2021 05:03:16

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-21T00:03:08', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'bb0f41c9-74ab-4a61-8a60-6ad28021defd'	System	21 Jan 2021 05:03:16
User entered 'No (N)'	System	21 Jan 2021 05:03:16

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-21T00:03:14', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'bb0f41c9-74ab-4a61-8a60-6ad28021defd' User entered '21 Jan 2021 00:03:14'	System	21 Jan 2021 05:03:16
	System	21 Jan 2021 05:03:16

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 05:51:15



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-28T00:02:10', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '221b9aba-d07e-44b5-8bf4-876450e56647' User entered 'No (N)'	System	28 Jan 2021 05:02:46
	System	28 Jan 2021 05:02:46

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-28T00:02:16', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '221b9aba-d07e-44b5-8bf4-876450e56647' User entered 'No (N)'	System	28 Jan 2021 05:02:46

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-01-28T00:02:21', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '221b9aba-d07e-44b5-8bf4-876450e56647' User entered '28 Jan 2021 00:02:21'	System	28 Jan 2021 05:02:46
	System	28 Jan 2021 05:02:46

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 05:51:15



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-02-04T11:24:31', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '58515de0-d5bb-4a45-a5cd-babcf8b018fe' User entered 'No (N)'	System	04 Feb 2021 16:24:47
	System	04 Feb 2021 16:24:47

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-02-04T11:24:35', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '58515de0-d5bb-4a45-a5cd-babcf8b018fe' User entered 'No (N)'	System	04 Feb 2021 16:24:47

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-02-04T11:24:40', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '58515de0-d5bb-4a45-a5cd-babcf8b018fe' User entered '04 Feb 2021 11:24:40'	System	04 Feb 2021 16:24:47
	System	04 Feb 2021 16:24:47

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-02-13T11:27:57', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '91e19fa0-4548-4651-8cfd-541a18a6c3ca' User entered 'No (N)'	System	13 Feb 2021 16:28:13
	System	13 Feb 2021 16:28:13

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-02-13T11:28:05', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '91e19fa0-4548-4651-8cfd-541a18a6c3ca' User entered 'No (N)'	System	13 Feb 2021 16:28:13
	System	13 Feb 2021 16:28:13



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-02-13T11:28:09', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '91e19fa0-4548-4651-8cfd-541a18a6c3ca' User entered '13 Feb 2021 11:28:09'	System	13 Feb 2021 16:28:13
	System	13 Feb 2021 16:28:13

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-02-18T09:44:12', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '2e4fb978-0d93-41a1-b828-fbb311f8a040'	System	18 Feb 2021 14:44:23
User entered 'No (N)'	System	18 Feb 2021 14:44:23

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-02-18T09:44:15', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '2e4fb978-0d93-41a1-b828-fbb311f8a040'	System	18 Feb 2021 14:44:23
User entered 'No (N)'	System	18 Feb 2021 14:44:23

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-02-18T09:44:19', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '2e4fb978-0d93-41a1-b828-fbb311f8a040' User entered '18 Feb 2021 09:44:19'	System	18 Feb 2021 14:44:23
	System	18 Feb 2021 14:44:23

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 05:51:15



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-02-28T15:52:08-05:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '2088ffc3-880b-4c0a-ae0-9165a6782c50'	System	28 Feb 2021 20:52:19
User entered 'No (N)'	System	28 Feb 2021 20:52:19

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-02-28T15:52:11-05:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '2088ffc3-880b-4c0a-ae0-9165a6782c50'	System	28 Feb 2021 20:52:19
User entered 'No (N)'	System	28 Feb 2021 20:52:19

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-02-28T15:52:16-05:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '2088ffc3-880b-4c0a-ae0-9165a6782c50'	System	28 Feb 2021 20:52:19
User entered '28 Feb 2021 20:52:16'	System	28 Feb 2021 20:52:19

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 05:51:15



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-03-04T08:42:27-05:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '390b1ea4-4c80-4939-987c-b7591292b619'	System	04 Mar 2021 13:42:57
User entered 'No (N)'	System	04 Mar 2021 13:42:57

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-03-04T08:42:47-05:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '390b1ea4-4c80-4939-987c-b7591292b619'	System	04 Mar 2021 13:42:57
User entered 'No (N)'	System	04 Mar 2021 13:42:57

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-03-04T08:42:51-05:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '390b1ea4-4c80-4939-987c-b7591292b619'	System	04 Mar 2021 13:42:57
User entered '04 Mar 2021 08:42:51'	System	04 Mar 2021 13:42:57

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-03-11T00:03:43-05:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'e6cc9a65-1300-4325-ade2-dde48e957fd3'	System	11 Mar 2021 05:04:59
User entered 'No (N)'	System	11 Mar 2021 05:04:59

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-03-11T00:03:48-05:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'e6cc9a65-1300-4325-ade2-dde48e957fd3'	System	11 Mar 2021 05:04:59
User entered 'No (N)'	System	11 Mar 2021 05:04:59



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-03-11T00:03:53-05:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'e6cc9a65-1300-4325-ade2-dde48e957fd3' User entered '11 Mar 2021 00:03:53'	System	11 Mar 2021 05:04:59
	System	11 Mar 2021 05:04:59

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-03-18T09:21:33-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'db441a85-2456-479d-b0b9-b756b0043445'	System	18 Mar 2021 13:21:45
User entered 'No (N)'	System	18 Mar 2021 13:21:45

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-03-18T09:21:36-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'db441a85-2456-479d-b0b9-b756b0043445'	System	18 Mar 2021 13:21:45
User entered 'No (N)'	System	18 Mar 2021 13:21:45

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-03-18T09:21:41-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'db441a85-2456-479d-b0b9-b756b0043445'	System	18 Mar 2021 13:21:45
User entered '18 Mar 2021 09:21:41'	System	18 Mar 2021 13:21:45

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 05:51:15



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-03-25T09:54:33-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '00e3f694-ba85-4583-8a36-d17168129d23'	System	25 Mar 2021 13:54:58
User entered 'No (N)'	System	25 Mar 2021 13:54:58

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-03-25T09:54:42-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '00e3f694-ba85-4583-8a36-d17168129d23'	System	25 Mar 2021 13:54:58
User entered 'No (N)'	System	25 Mar 2021 13:54:58

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-03-25T09:54:53-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '00e3f694-ba85-4583-8a36-d17168129d23'	System	25 Mar 2021 13:54:58
User entered '25 Mar 2021 09:54:53'	System	25 Mar 2021 13:54:58

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 05:51:15



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-05T11:23:24-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'd30b19cb-c6c9-4738-b6ee-39d99c6131a1' User entered 'Yes (Y)'	System	05 Apr 2021 15:24:51
	System	05 Apr 2021 15:24:51

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-05T11:23:30-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'd30b19cb-c6c9-4738-b6ee-39d99c6131a1' User entered 'No (N)'	System	05 Apr 2021 15:24:51
	System	05 Apr 2021 15:24:51

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-05T11:23:49-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'd30b19cb-c6c9-4738-b6ee-39d99c6131a1' User entered 'No (N)'	System	05 Apr 2021 15:24:51
	System	05 Apr 2021 15:24:51

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-05T11:23:58-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'd30b19cb-c6c9-4738-b6ee-39d99c6131a1' User entered 'Yes (Y)'	System	05 Apr 2021 15:24:51
	System	05 Apr 2021 15:24:51

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-05T11:24:33-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'd30b19cb-c6c9-4738-b6ee-39d99c6131a1'	System	05 Apr 2021 15:24:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Apr 2021 15:24:51

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-05T11:24:40-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'd30b19cb-c6c9-4738-b6ee-39d99c6131a1' User entered '05 Apr 2021 11:24:40'	System	05 Apr 2021 15:24:51
	System	05 Apr 2021 15:24:51

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 05:51:15



**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 05:51:15

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-12T12:09:52-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '035c8978-20e1-4f06-a7a7-5a1387f5f1b3'	System	12 Apr 2021 16:15:11
User entered 'No (N)'	System	12 Apr 2021 16:15:11

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-12T12:09:57-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '035c8978-20e1-4f06-a7a7-5a1387f5f1b3'	System	12 Apr 2021 16:15:11
User entered 'No (N)'	System	12 Apr 2021 16:15:11

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-12T12:10:02-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '035c8978-20e1-4f06-a7a7-5a1387f5f1b3'	System	12 Apr 2021 16:15:11
User entered '12 Apr 2021 12:10:02'	System	12 Apr 2021 16:15:11

**US3372348**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-15T00:03:25-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3eb48215-fe88-4828-852f-101ff0f6ff08'	System	15 Apr 2021 04:04:28
User entered 'No (N)'	System	15 Apr 2021 04:04:28



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-15T00:03:29-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3eb48215-fe88-4828-852f-101ff0f6ff08'	System	15 Apr 2021 04:04:28
User entered 'No (N)'	System	15 Apr 2021 04:04:28

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-15T00:03:34-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '3eb48215-fe88-4828-852f-101ff0f6ff08'	System	15 Apr 2021 04:04:28
User entered '15 Apr 2021 00:03:34'	System	15 Apr 2021 04:04:28

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-22T07:15:14-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f128df57-0c8e-4ce6-85b4-f5512782d0c1'	System	22 Apr 2021 11:15:29
User entered 'No (N)'	System	22 Apr 2021 11:15:29

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-22T07:15:19-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f128df57-0c8e-4ce6-85b4-f5512782d0c1'	System	22 Apr 2021 11:15:29
User entered 'No (N)'	System	22 Apr 2021 11:15:29

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-22T07:15:24-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'f128df57-0c8e-4ce6-85b4-f5512782d0c1' User entered '22 Apr 2021 07:15:24'	System	22 Apr 2021 11:15:29
	System	22 Apr 2021 11:15:29



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-29T08:13:47-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '0f85d74d-bb1a-41ef-92b5-da3611433122'	System	29 Apr 2021 12:14:00
User entered 'No (N)'	System	29 Apr 2021 12:14:00

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

Have you been exposed to someone with 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 (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-29T08:13:50-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '0f85d74d-bb1a-41ef-92b5-da3611433122'	System	29 Apr 2021 12:14:00
User entered 'No (N)'	System	29 Apr 2021 12:14:00

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-04-29T08:13:54-04:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: '0f85d74d-bb1a-41ef-92b5-da3611433122' User entered '29 Apr 2021 08:13:54'	System	29 Apr 2021 12:14:00
	System	29 Apr 2021 12:14:00

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 05:51:15



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 05:51:15



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 05:51:15



**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 05:51:15

**US3372348**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:17:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:51:15
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 05:51:15

US3372348

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:17:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:04:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-02-28T15:52:33-05:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ef519765-e72f-407b-96e9-67a0ceb7e846'	System	28 Feb 2021 20:52:39
User entered 'No (N)'	System	28 Feb 2021 20:52:39

**US3372348**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:04:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A3E103B-98B0-4CDC-AD23-18BEEF42638D)', Time: '2021-02-28T15:52:38-05:00', User OID: 'PatientReportedOutcome (US3372348)', ODM File OID: 'ef519765-e72f-407b-96e9-67a0ceb7e846'	System	28 Feb 2021 20:52:39
User entered '28 Feb 2021 20:52:38'	System	28 Feb 2021 20:52:39

**US3372348**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	08 Dec 2020 19:11:18
	(b) (4)	

**US3372348**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered '8 Dec 2020'	(b) (4) Danielle Theodore (b) (4)	08 Dec 2020 19:11:18

**US3372348**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	08 Dec 2020 19:11:18



US3372348

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	08 Dec 2020 19:11:18

**US3372348**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:45:05
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	08 Dec 2020 19:11:26

**US3372348**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:31:49
User entered 'I'	System	08 Dec 2020 19:11:26

**US3372348**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	11 Jan 2021 16:35:46

**US3372348**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered '11 Jan 2021'	(b) (4) Danielle Theodore (b) (4) (b) (4)	11 Jan 2021 16:35:46

**US3372348**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	11 Jan 2021 16:35:46

US3372348

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:17:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	11 Jan 2021 16:35:46

**US3372348**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:45:05
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	11 Jan 2021 16:35:57
	(b) (4)	



**US3372348**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User entered 'I'	System	11 Jan 2021 16:35:57

**US3372348**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	10 Feb 2021 14:41:45

**US3372348**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered '10 Feb 2021'	(b) (4) Danielle Theodore (b) (4)	10 Feb 2021 14:41:45
	(b) (4)	

**US3372348**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	10 Feb 2021 14:41:45
	(b) (4)	

**US3372348**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	10 Feb 2021 14:41:45

**US3372348**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:45:05
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	10 Feb 2021 14:41:50

**US3372348**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User entered 'I'	System	10 Feb 2021 14:41:50

**US3372348**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:29:38
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	12 Mar 2021 16:59:18



**US3372348**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:29:38
User entered '12 Mar 2021'	(b) (4) Danielle Theodore (b) (4)	12 Mar 2021 16:59:18
	(b) (4)	

**US3372348**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:29:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	12 Mar 2021 16:59:18

**US3372348**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:29:38
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	12 Mar 2021 16:59:18

**US3372348**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:29:38
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	12 Mar 2021 17:00:31

**US3372348**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User entered 'I'	System	12 Mar 2021 17:00:31

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:38

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:38

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[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 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:38



**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User entered 'VISIT4'	System	29 Mar 2021 21:39:38

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:40:18

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:40:18

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '08:51'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:40:18

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User entered '29 Mar 2021 08:51'	System	29 Mar 2021 21:40:18

US3372348

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	29 Mar 2021 21:40:30
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	29 Mar 2021 21:40:30
User entered '36.4' C reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 21:40:30
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	29 Mar 2021 21:40:18
User entered '97.6' C	(b) (4), (b) (6)	29 Mar 2021 21:40:18

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:40:18

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'forehead'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:40:18



**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '91'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:40:18

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User entered 'bpm'	System	29 Mar 2021 21:40:18

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '16'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:40:18

US3372348

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User entered 'breaths/min'	System	29 Mar 2021 21:40:18

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '127'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:40:18

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User entered 'mmHg'	System	29 Mar 2021 21:40:18

US3372348

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '76'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:40:18

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User entered 'mmHg'	System	29 Mar 2021 21:40:18



**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:17:58**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:40:38

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:17:58**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:40:38

US3372348

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:41:00

US3372348

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:41:00

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '08:51'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:41:00

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User entered '29 Mar 2021 08:51'	System	29 Mar 2021 21:41:00



**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:41:04

**US3372348**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:11:57
User entered 'I'	System	29 Mar 2021 21:41:04

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:20:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:03:09

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:20:41
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:03:09

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:20:41
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:03:09

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 19:03:09

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:17:58

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:04:38
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:02:30

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:17:58**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:53
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 20:36:11
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:46:49



**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:17:58**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:02:30

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:17:58

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:54:53
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 07:14:00
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 20:36:14
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	13 Apr 2021 20:36:11
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:02:49
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:46:49

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:17:58

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:04:38
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:02:30

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:17:58**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:04:38
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:02:30

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:17:58**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:04:38
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:02:30

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:17:58**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:04:38
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:02:30

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:17:58**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:02:30

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:17:58**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered '1'	System	27 Jan 2021 19:02:30



**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'I'	System	27 Jan 2021 19:02:30

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:17:58**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:17:58**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:17:58**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered empty.	System	27 Jan 2021 19:05:20
DataPoint set to visible.	System	27 Jan 2021 19:02:30

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:17:58**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:17:58**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:17:58**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered empty.	System	27 Jan 2021 19:05:20
DataPoint set to visible.	System	27 Jan 2021 19:02:30

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	27 Jan 2021 19:05:20



**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '11:25'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered '27 Jan 2021 11:25'	System	27 Jan 2021 19:05:20

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '75'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20



**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'bpm'	System	27 Jan 2021 19:05:20

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '17'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'breaths/min'	System	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '148'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'mmHg'	System	27 Jan 2021 19:05:20

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '102'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'mmHg'	System	27 Jan 2021 19:05:20

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:17:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20



**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:17:58**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:17:58**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered empty.	System	27 Jan 2021 19:05:20
DataPoint set to visible.	System	27 Jan 2021 19:02:30

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '12:45'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered '27 Jan 2021 12:45'	System	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20



**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '74'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'bpm'	System	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '18'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'breaths/min'	System	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '186'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'mmHg'	System	27 Jan 2021 19:05:20



**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:53:01
User entered '106'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'mmHg'	System	27 Jan 2021 19:05:20

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:17:58**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:14:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:24

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:14:20
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:24

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:50:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:38

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:50:53
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:38

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:50:53
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:38

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'mRNA-1273'	System	27 Jan 2021 19:05:38
DataPoint set to visible.	System	27 Jan 2021 19:02:30



US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:50:53
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:38

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:50:53
User entered '12:15'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:38

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered '27 Jan 2021 12:15'	System	27 Jan 2021 19:05:38

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:50:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:05:38

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'ONCE'	System	27 Jan 2021 19:05:38

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'INTRAMUSCULAR'	System	27 Jan 2021 19:05:38

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:02:44

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:10:26
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:02:44



**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:10:26
User entered '11:11'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:02:44

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered '27 Jan 2021 11:11'	System	27 Jan 2021 19:02:44

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:17:58**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:50:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:02:55

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:17:58**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:50:11
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:02:55

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:17:58**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:50:11
User entered '11:09'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:02:55

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:17:58**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered '27 Jan 2021 11:09'	System	27 Jan 2021 19:02:55

US3372348

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:45:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:02:58

**US3372348**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'I'	System	27 Jan 2021 19:02:58



**US3372348**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:18
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	03 Feb 2021 15:37:53

**US3372348**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:18
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered '3 Feb 2021'	(b) (4) Danielle Theodore (b) (4) (b) (4)	03 Feb 2021 15:37:53

**US3372348**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:18
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	03 Feb 2021 15:37:53

**US3372348**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:18
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:42:35
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	03 Feb 2021 15:37:53

**US3372348**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:18
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:45:05
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	03 Feb 2021 15:37:59
	(b) (4)	

**US3372348**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:18
User entered 'I'	System	03 Feb 2021 15:37:59

**US3372348**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:18
User entered '1'	System	03 Feb 2021 15:37:59
DataPoint set to visible.	System	03 Feb 2021 15:37:59

**US3372348**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:00:06



**US3372348**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:00:06

**US3372348**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:00:06

**US3372348**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'OLD29'	System	24 Feb 2021 16:00:06

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

US3372348

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '13:05'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered '23 Feb 2021 13:05'	System	24 Feb 2021 16:01:46



**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

US3372348

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '101'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'bpm'	System	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '18'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'breaths/min'	System	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '151'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46



**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'mmHg'	System	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '97'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'mmHg'	System	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '14:10'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered '23 Feb 2021 14:10'	System	24 Feb 2021 16:01:46



**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

US3372348

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '83'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'bpm'	System	24 Feb 2021 16:01:46

US3372348

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '17'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

US3372348

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'breaths/min'	System	24 Feb 2021 16:01:46

US3372348

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:17:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '154'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46



**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'mmHg'	System	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '93'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'mmHg'	System	24 Feb 2021 16:01:46

**US3372348**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:17:58**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:50

**US3372348**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:17:58**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:01:50

**US3372348**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:02:08

**US3372348**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:02:08

US3372348

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:02:08



**US3372348**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'mRNA-1273'	System	24 Feb 2021 16:02:08
DataPoint set to visible.	System	03 Feb 2021 15:37:59

US3372348

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:02:08

**US3372348**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered '13:39'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:02:08

**US3372348**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered '23 Feb 2021 13:39'	System	24 Feb 2021 16:02:08

**US3372348**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:02:08

US3372348

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:17:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'ONCE'	System	24 Feb 2021 16:02:08

**US3372348**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:17:58**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 16:02:08

**US3372348**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 21:01:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:02:11



**US3372348**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:32:38
User entered 'I'	System	24 Feb 2021 16:02:11

**US3372348**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:31
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:29:38
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	02 Mar 2021 15:12:19

**US3372348**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:31
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:29:38
User entered '2 Mar 2021'	(b) (4) Danielle Theodore (b) (4) (b) (4)	02 Mar 2021 15:12:19

**US3372348**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:31
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:29:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	02 Mar 2021 15:12:19

**US3372348**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:17:58**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:31
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:29:38
User entered empty.	(b) (4) Danielle Theodore (b) (4)	02 Mar 2021 15:12:19
	(b) (4)	

**US3372348**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:31
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:29:38
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	02 Mar 2021 15:12:32

**US3372348**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:17:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:31
User entered 'I'	System	02 Mar 2021 15:12:32

**US3372348**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:38:36



US3372348

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:17:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Mar 2021 21:38:42
User entered '29 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 21:38:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Mar 2021 21:38:36
User entered '29 Feb 2021' (non-conformant).	(b) (4), (b) (6)	29 Mar 2021 21:38:36

**US3372348**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:38:36

**US3372348**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:17:58**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Mar 2021 21:38:36

**US3372348**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:07

**US3372348**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:07

**US3372348**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '08:40'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:07

**US3372348**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 08:40'	System	29 Mar 2021 21:39:07

**US3372348**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:07



**US3372348**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:07

**US3372348**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'forehead'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:07

**US3372348**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '91'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:07

**US3372348**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Mar 2021 21:39:07

US3372348

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '16'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:07

**US3372348**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Mar 2021 21:39:07

US3372348

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:17:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '127'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:07

**US3372348**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 21:39:07



**US3372348**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '76'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:07

**US3372348**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:17:58**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 21:39:07

US3372348

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:17:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:12

**US3372348**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:17:58**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:12

**US3372348**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:23

US3372348

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:17:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:23

**US3372348**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 14:30:39
User entered '08:51'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:39:23

**US3372348**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:17:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 08:51'	System	29 Mar 2021 21:39:23



**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 17:17:58**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:17
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:53:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:17:50

US3372348

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone related signs and symptoms, PT: Spinal pain, LLT: Pain in thoracic spine - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Feb 2021 14:29:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 14:29:01
Data point term sent to Coder	System	16 Feb 2021 15:19:15
User entered 'Back pain - left sided thoracolumbar - increased from baseline'	(b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered '15 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

US3372348

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:58

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4) System	19 Feb 2021 17:33:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 17:33:09
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Feb 2021 15:19:08
User entered '10:37'	(b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 17:33:09
User entered '15 Nov 2020 10:37'	System	16 Feb 2021 15:19:08



**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08



**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

US3372348

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

US3372348

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08



**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:19:08

US3372348

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:17:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	(b) (4) System	19 Feb 2021 17:33:30
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	16 Feb 2021 15:19:08
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:33:30
User entered 'Ibuprofen'	(b) (4), (b) (6)	16 Feb 2021 15:19:08



**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:34:06
User entered 'IBUPROFEN' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 17:33:30
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Feb 2021 15:19:08

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Feb 2021 15:19:08

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 14:06:49
User entered		
'USA-US056-2021-mRNA-1273-P301000014'	System	06 Apr 2021 14:06:36
User entered 'New'	(b) (4), (b) (6)	06 Apr 2021 14:06:36

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	05 Apr 2021 20:16:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 20:16:34
Data point term sent to Coder	System	05 Apr 2021 20:15:42
User entered 'Myocardial Infarction'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered '02 Apr 2021' reason for change: Data Entry Error	Peter Jacob (b) (4)	14 Apr 2021 19:43:00
	(b) (4)	
User entered '2 Apr 2021'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:17:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 20:14:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered '04 Apr 2021' reason for change: Data Entry Error	Peter Jacob (b) (4)	14 Apr 2021 19:43:00
	(b) (4)	
User entered '4 Apr 2021'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:17:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Mary Sergalis (b) (4)	05 Apr 2021 20:14:53



US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

Death

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered 'I'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered '02 Apr 2021' reason for change: Data Entry Error	Peter Jacob (b) (4)	14 Apr 2021 19:43:00
	(b) (4)	
User entered '2 Apr 2021'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered '04 Apr 2021' reason for change: Data Entry Error	Peter Jacob (b) (4)	14 Apr 2021 19:42:36
	(b) (4)	
User entered '4 Apr 2021'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	13 Apr 2021 19:01:11
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	13 Apr 2021 19:01:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	13 Apr 2021 19:01:11
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	05 Apr 2021 20:14:53
User entered 'Unknown (UNK)'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered '3' reason for change: Data Entry Error	Mary Sergalis (b) (4)	13 Apr 2021 19:01:11
User entered empty.	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product and study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:21:22
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product and study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' answered with 'updated' (Site from Safety).	Mary Sergalis (b) (4)	13 Apr 2021 19:01:34
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	13 Apr 2021 19:01:11
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product and study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:31:48
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product and study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:21:23
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product and study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' answered with 'updated' (Site from Safety).	Mary Sergalis (b) (4)	13 Apr 2021 19:01:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	13 Apr 2021 19:01:11
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product and study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:31:54
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

None

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	14 Apr 2021 18:30:14
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 18:30:14
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	14 Apr 2021 18:29:58
User entered '1'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:15:55
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'Data updated.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 18:30:34
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:32:12
User entered '0'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53



**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:29:58
User entered '0'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

US3372348

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for providing medical records/discharge summary. Please confirm if there are any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Thank you' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:02:02
Query 'PV Query: Thank you for providing medical records/discharge summary. Please confirm if there are any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Thank you' answered with 'no further relevant information to report' (Site from Safety).	Mary Sergalis (b) (4)	29 Apr 2021 15:23:37
User opened query 'PV Query: Thank you for providing medical records/discharge summary. Please confirm if there are any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Thank you' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 14:17:59
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:16:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:17:58

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'Data updated.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 18:30:43
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 17:21:25
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'COVID 19 PCR completed on 02-APR-2021 with Presumptive Negative' (Site from Safety).	Mary Sergalis (b) (4)	13 Apr 2021 19:03:34
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:32:21
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:32:05
User entered 'Subject informed the site that they were admitted to the hospital for Myocardial Infarct on 02-APR-2021. Discharged on 04-APR-2021. No further available at this time. Medical records to be requested'	Mary Sergalis (b) (4)	05 Apr 2021 20:14:53

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 20:14:53

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 20:14:53

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 19:01:11
User entered '0'	System	05 Apr 2021 20:14:53



**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Hypoaesthesia, LLT: Numbness of upper extremities - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:24:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:24:08
Data point term sent to Coder	System	14 Apr 2021 20:23:06
User entered 'Left Arm Numbness'	(b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:17:58

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User entered empty.	System	14 Apr 2021 20:22:18



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User entered empty.	System	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18



**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18



**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18



**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User entered '0'	System	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57
User entered '1'	System	14 Apr 2021 20:22:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:57

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Substernal chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:24:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:24:56
Data point term sent to Coder	System	14 Apr 2021 20:24:08
User entered 'Substernal Chest Pain'	(b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18



**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User entered empty.	System	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User entered empty.	System	14 Apr 2021 20:23:18



**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

US3372348

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:17:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18



**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18



**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User entered '0'	System	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17
User entered 'I'	System	14 Apr 2021 20:23:18

**US3372348**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:17:58**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:17



US3372348

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:17:58

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:17
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:51:57
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 17:56:09

US3372348

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Sep 2020 17:58:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:58:46
Data point term sent to Coder	System	28 Sep 2020 17:57:25
User entered 'ibuprofen'	Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:56:36

**US3372348**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:56:36

**US3372348**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
User entered 'chronic lower back pain'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:56:36

**US3372348**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
User entered '800'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 17:56:36

US3372348

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	28 Sep 2020 17:56:36
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 17:56:36
	(b) (4)	

**US3372348**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
	(b) (4)	
User entered 'three times daily (TID)'	Peter Jacob (b) (4)	28 Sep 2020 17:56:36
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:56:36

**US3372348**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:56:36

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 17:56:36
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
	(b) (4)	
User entered 'un Dec 2019'	Peter Jacob (b) (4)	28 Sep 2020 17:56:36
	(b) (4)	

**US3372348**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:56:36

**US3372348**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	28 Sep 2020 17:56:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:17:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	28 Sep 2020 17:56:36
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:36:36
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:56:36



**US3372348**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Sep 2020 17:56:36

**US3372348**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 17:56:36

**US3372348**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 17:56:36

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:17:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:17
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:28:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 18:28:03
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:22:26
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Sep 2020 17:56:03

US3372348

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:17:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:28:30

US3372348

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:17:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Chest X-Ray'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:28:30

**US3372348**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:28:30

US3372348

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:17:58

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:28:30



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:17:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:29:26

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:17:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Cardiac Catheterization / PCI'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:29:26

US3372348

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:17:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:29:26

US3372348

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:17:58

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:29:26

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'USA-US056-2021-MRNA-1273-P301000014'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36



**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

US3372348

Folder: SAE USA-US056-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Mira'	System	06 Apr 2021 14:06:36

US3372348

Folder: SAE USA-US056-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Baron'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered '2277 Palm beach Lakes Blvd'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'West Palm Beach'	System	06 Apr 2021 14:06:36



**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered '33409'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 17:21:38
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
User entered 'US'	(b) (4) System	06 Apr 2021 14:07:51

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Apr 2021 13:14:30
User entered '2'	System	14 Apr 2021 17:21:46
User entered '1'	System	06 Apr 2021 14:07:51

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'USA-US056-2021-MRNA-1273-P301000014'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:36



**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

US3372348

Folder: SAE USA-US056-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Mira'	System	06 Apr 2021 14:06:36

US3372348

Folder: SAE USA-US056-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Baron'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered '2277 Palm beach Lakes Blvd'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'West Palm Beach'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered '33409'	System	06 Apr 2021 14:06:36



**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 17:21:38
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
User entered 'US'	(b) (4) System	06 Apr 2021 14:07:51

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Apr 2021 13:14:30
User entered '2'	System	14 Apr 2021 17:21:46
User entered '1'	System	06 Apr 2021 14:07:51

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:17:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
User entered '06/Apr/2021 14:07'	(b) (4) System	06 Apr 2021 14:07:51

US3372348

Folder: SAE USA-US056-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:17:58

**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)	14 Apr 2021 17:21:38
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 14:07:51

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'USA-US056-2021-MRNA-1273-P301000014'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36



**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Mira'	System	06 Apr 2021 14:06:36

US3372348

Folder: SAE USA-US056-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:17:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Baron'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered '2277 Palm beach Lakes Blvd'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'West Palm Beach'	System	06 Apr 2021 14:06:36



**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered '33409'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 17:21:38
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
User entered 'US'	(b) (4) System	06 Apr 2021 14:07:51

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Apr 2021 13:14:30
User entered '2'	System	14 Apr 2021 17:21:46
User entered '1'	System	06 Apr 2021 14:07:51

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:17:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 18:07:07
User entered '14/Apr/2021 13:21'	(b) (4) System	14 Apr 2021 17:21:46

US3372348

Folder: SAE USA-US056-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:17:58

**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)	14 Apr 2021 18:07:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:21:46

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'USA-US056-2021-MRNA-1273-P301000014'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36



**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'No (N)'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Mira'	System	06 Apr 2021 14:06:36

US3372348

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'Baron'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered '2277 Palm beach Lakes Blvd'	System	06 Apr 2021 14:06:36



**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered 'West Palm Beach'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:07:45
User entered '33409'	System	06 Apr 2021 14:06:36

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 17:21:38
User signature succeeded.	Mira Baron (b) (4)	06 Apr 2021 15:07:57
User entered 'US'	(b) (4) System	06 Apr 2021 14:07:51

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:17:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Apr 2021 13:14:30
User entered '2'	System	14 Apr 2021 17:21:46
User entered '1'	System	06 Apr 2021 14:07:51

**US3372348**

**Folder: SAE USA-US056-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:17:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Apr 2021 13:18:22
User entered '15/Apr/2021 06:14'	(b) (4) System	15 Apr 2021 13:14:30

US3372348

Folder: SAE USA-US056-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:17:58

**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)	15 Apr 2021 13:18:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:14:30