

US3492178 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:00:24

All time stamps listed in this document are displayed in GMT

US3492178

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 03:57:18

Generated On: 10 Jun 2021 08:00:24

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[Participant ID](#)

US3492178

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

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US3492178

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	68
Age Units	YEARS
Age (Derived)	68
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Date of Informed Consent ( <i>dd MMM yyyy</i> )	17 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 03:57:50

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Condition	FATTY LIVER
Start date (dd MMM yyyy)	UN UNK 2015
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Condition	RESTLESS LEGS SYNDROME
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 (5)

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Condition	VITAMIN D3 DEFICIENCY
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)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	17 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	09:08 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 09:08
Height ( <i>xxx.x</i> )	151.8 cm
Weight ( <i>xxx.x</i> )	60.3 kg
BMI ( <i>xxx.x</i> )	26.16820 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:57:50

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Date of assessment (*dd MMM yyyy*) 17 SEP 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2001

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 03:57:50

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

What was the date of randomization? (dd MMM yyyy) 17 SEP 2020

What was the participant's randomization number? 190978

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) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	09:08 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 09:08
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	10:51 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 10:51
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 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) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

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) 17 SEP 2020

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

Treatment Date and Time (derived) 17 SEP 2020 10:23

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 SEP 2020

Collection time (00:00-23:59)

09:53 (24 HR)

Collection date and time (derived)

17 SEP 2020 09:53

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:00	17 SEP 2020 10:00
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 10:52

PC Open Date & Time

17 SEP 2020 10:43

PC Close Date & Time

17 SEP 2020 13:13

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**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 97.9 °F

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

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

PC Time Stamp	17 SEP 2020 19:57
PC Open Date & Time	17 SEP 2020 14:08
PC Close Date & Time	18 SEP 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 18 SEP 2020 19:49

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**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 97.1 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 19 SEP 2020 19:37

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**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

20 SEP 2020 19:56

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:24

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

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

21 SEP 2020 20:20

---

PC Open Date & Time

21 SEP 2020 12:00

---

PC Close Date & Time

22 SEP 2020 11:59

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US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**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

97.6 °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

22 SEP 2020 19:31

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**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

23 SEP 2020 19:22

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**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

17 SEP 2020 10:53

PC Open Date & Time

17 SEP 2020 10:43

PC Close Date & Time

17 SEP 2020 13:13

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**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

17 SEP 2020 19:59

PC Open Date & Time

17 SEP 2020 14:08

PC Close Date & Time

18 SEP 2020 11:59



US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**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

18 SEP 2020 19:51

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**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

19 SEP 2020 19:38

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 19:57

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**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

21 SEP 2020 20:21

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 19:32

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**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

23 SEP 2020 19:23

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**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 ☐

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 10:55
PC Open Date & Time	17 SEP 2020 10:43
PC Close Date & Time	17 SEP 2020 13:13



US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**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 ☐

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 20:00
PC Open Date & Time	17 SEP 2020 14:08
PC Close Date & Time	18 SEP 2020 11:59

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**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 ☒

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

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

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**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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US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 19:39
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2245

EAB) (1725)

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 19:58
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59



US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 20:23
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 19:33
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**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 ☒

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

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

US3492178

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3492178

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3492178

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3492178

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492178

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3492178

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492178

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

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 OCT 2020
Time of assessment (00:00-23:59)	08:12 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 08:12
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

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 OCT 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 10:10
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3492178

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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



US3492178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

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 OCT 2020

What was the treatment time? (00:00-23:59) 09:40 (24 HR)

Treatment Date and Time (derived) 15 OCT 2020 09:40

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

US3492178

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

08:36 (24 HR)

Collection date and time (derived)

15 OCT 2020 08:36

US3492178

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Collection date (dd MMM yyyy)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:43	15 OCT 2020 08:43
Nasopharyngeal Swab 2	No		

US3492178

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp 15 OCT 2020 10:01

PC Open Date & Time 15 OCT 2020 10:00

PC Close Date & Time 15 OCT 2020 12:30

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**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 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	15 OCT 2020 20:08
PC Open Date & Time	15 OCT 2020 13:25
PC Close Date & Time	16 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 19:12

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 20:05

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59



US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**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 OCT 2020 19:51

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 18:52

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 19:03

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**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.

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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

21 OCT 2020 19:30

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 10:02

PC Open Date & Time

15 OCT 2020 10:00

PC Close Date & Time

15 OCT 2020 12:30

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**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

15 OCT 2020 20:09

PC Open Date & Time

15 OCT 2020 13:25

PC Close Date & Time

16 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**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 OCT 2020 19:13

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**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 OCT 2020 20:05

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59



US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**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 OCT 2020 19:51

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**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 OCT 2020 18:52

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**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 OCT 2020 19:04

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**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 OCT 2020 19:31

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**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 ☐

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 10:03
PC Open Date & Time	15 OCT 2020 10:00
PC Close Date & Time	15 OCT 2020 12:30

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**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 ☐

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 20:10
PC Open Date & Time	15 OCT 2020 13:25
PC Close Date & Time	16 OCT 2020 11:59



US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**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 ☒

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 19:14
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**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 ☒

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 20:06
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**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 ☒

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 19:52
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 18:53
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59



US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

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 ☒

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 19:04
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**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 ☒

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 19:31
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3492178

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3492178

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492178

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3492178

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3492178

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3492178

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492178

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

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

US3492178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	08:17 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 08:17
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492178

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 NOV 2020

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

US3492178

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 NOV 2020

Collection time (00:00-23:59)

08:25 (24 HR)

Collection date and time (derived)

12 NOV 2020 08:25

US3492178

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492178

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 11:07:04
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59



US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

<b>TIMEPOINT</b>	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	25 NOV 2020 11:21:54
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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	01 DEC 2020 12:35:24
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 10:57:19

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 10:37:55
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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	22 DEC 2020 16:41:40
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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30 DEC 2020 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	02 JAN 2021 12:27:12
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59



US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	13 JAN 2021 08:05:01
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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	16 JAN 2021 21:03:49
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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

24 JAN 2021 10:42:35

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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

01 FEB 2021 20:41:34

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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

08 FEB 2021 07:38:22

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	16 FEB 2021 19:15:22
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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

23 FEB 2021 09:33:30

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 09:54:10

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59



US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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

07 MAR 2021 11:21:06

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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

13 MAR 2021 23:07:25

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 23:01:09

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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31 MAR 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 16:19:13

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 12:57:37

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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

18 APR 2021 16:27:46

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59



US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 222

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

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

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

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

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

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

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

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 APR 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 APR 2021 23:59
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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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05 MAY 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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="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"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAY 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUN 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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°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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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



US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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28 JUL 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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°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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59



US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59
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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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08 SEP 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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25 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 SEP 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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27 OCT 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59



US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59



US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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09 FEB 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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°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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 MAR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 MAR 2022 23:59
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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 APR 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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16 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 APR 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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25 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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02 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUL 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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°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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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13 JUL 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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27 JUL 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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03 AUG 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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24 AUG 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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07 SEP 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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"/>

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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05 OCT 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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22 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 OCT 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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02 NOV 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Open Date & Time](#)

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05 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2022 23:59

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US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

**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 ☐

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

US3492178

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

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

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[Patient Cloud Close Date & Time](#)

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23 NOV 2022 23:59

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**US3492178**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 08:00:24**

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		02 MAR 2021 09:53:49

US3492178

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3492178

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492178

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3492178

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:57:49

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492178

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

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*

US3492178

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492178

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3492178

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492178

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 16:29:03

Generated On: 10 Jun 2021 08:00:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 APR 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



US3492178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 16:29:03

Generated On: 10 Jun 2021 08:00:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 APR 2021
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	13 APR 2021 08:15
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492178

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 16:29:03

Generated On: 10 Jun 2021 08:00:24

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.*

US3492178

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 16:29:03

Generated On: 10 Jun 2021 08:00:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 APR 2021
Collection time (00:00-23:59)	08:27 (24 HR)
Collection date and time (derived)	13 APR 2021 08:27

US3492178

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:48:07

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492178

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:00:24

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

**US3492178**

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

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

**Generated On: 10 Jun 2021 08:00:24**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3492178

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:57:49

Generated On: 10 Jun 2021 08:00:24

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

Visit date (dd MMM yyyy)	15 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3492178

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Date of updated informed consent ( <i>dd MMM yyyy</i> )	15 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> )	15 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



US3492178

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 03:57:49

Generated On: 10 Jun 2021 08:00:24

Height	
Weight	
BMI (xxx.x)	

US3492178

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 03:57:49

Generated On: 10 Jun 2021 08:00:24

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 JAN 2021
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 10:55
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3492178

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 03:57:49

Generated On: 10 Jun 2021 08:00:24

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 JAN 2021
Time of assessment (00:00-23:59)	12:36 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 12:36
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3492178

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:57:49

Generated On: 10 Jun 2021 08:00:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 JAN 2021

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

US3492178

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

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 03:57:49

Generated On: 10 Jun 2021 08:00:24

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) 15 JAN 2021

What was the treatment time? (00:00-23:59) 12:03 (24 HR)

Treatment Date and Time (derived) 15 JAN 2021 12:03

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

What was the frequency of the study treatment dosing? ONCE

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

US3492178

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:57:49

Generated On: 10 Jun 2021 08:00:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00-23:59)	11:21 (24 HR)
Collection date and time (derived)	15 JAN 2021 11:21

US3492178

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 03:57:49

Generated On: 10 Jun 2021 08:00:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	11:27
Collection Date and Time (derived)	15 JAN 2021 11:27

US3492178

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:57:49

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3492178

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3492178

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:57:50

Generated On: 10 Jun 2021 08:00:24

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

US3492178

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3492178

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 FEB 2021
Time of assessment (00:00-23:59)	10:03 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 10:03
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3492178

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

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)	12 FEB 2021
Time of assessment (00:00-23:59)	11:07 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 11:07
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input checked="" type="checkbox"/>
If Other, specify	TYMPANIC
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3492178

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

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.*

US3492178

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

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) 12 FEB 2021

What was the treatment time? (00:00-23:59) 10:30 (24 HR)

Treatment Date and Time (derived) 12 FEB 2021 10:30

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

US3492178

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3492178

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:48:07

Generated On: 10 Jun 2021 08:00:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3492178

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:48:07

Generated On: 10 Jun 2021 08:00:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492178

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3492178

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	12 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	11:29 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 11:29
Temperature ( <i>xxx.x</i> )	98.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse ( <i>xxx</i> )	63 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492178

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

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.*

US3492178

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	12 MAR 2021
Collection time ( <i>00:00-23:59</i> )	11:29 (24 HR)
Collection date and time (derived)	12 MAR 2021 11:29

US3492178

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 03:57:18

Generated On: 10 Jun 2021 08:00:24

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3492178

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

AEID

Adverse event

PAIN FROM BUNION TO RIGHT  
FOOT

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)

17 SEP 2020

Start time (00:00-23:59)

12:00 (24 HR)

AE start date and time (derived)

17 SEP 2020 12:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 SEP 2020

End time (00:00-23:59)

22:00 (24 HR)

AE End Date and Time (derived)

18 SEP 2020 22:00

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)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

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

US3492178

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

AEID	USA-US101-2021-MRNA-1273-P30 1000003
Adverse event	APPENDICITIS/PERFORATED APPENDIX, S/P APPENDECTOMY
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)	4 JAN 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)	11 JAN 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)	7 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	11 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

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

US3492178

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

---

PARTICIPANT SEEN IN  
EMERGENCY ROOM FOR RIGHT  
LOWER QUADRANT PAIN ON  
07JAN2021. CT SCAN OF THE  
ABDOMEN ON 7JAN2021  
SHOWED PERFORATION OF  
APPENDIX. PARTICIPANT WAS  
ADMITTED INTO HOSPITAL  
FOR APPENDICITIS.  
LAPAROSCOPIC  
APPENDECTOMY PERFORMED  
ON 07JAN2021. PARTICIPANT  
WAS DISCHARGED WITH  
AMOXICILLIN / CLAVULANATE  
POTASSIUM 875/125 1 TAB PO  
BID X 10 DAYS,  
HYDROCODONE 5/325 1 TAB PO  
Q 4H PRN

---

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

---

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 03:57:49

Generated On: 10 Jun 2021 08:00:24

---

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

Yes ☒

No ☐

---

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

---

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Name of Medication ALLEGRA

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONCE DAILY, AS NEEDED

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

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EAB) (1725)

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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Name of Medication RED YEAST RICE

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 1200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 01:48:06

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Mar 2021 01:48:06

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Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Mar 2021 01:48:06

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Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Name of Medication VITAMIN D3

Prophylaxis Yes ☐  
No ☒

Indication VITAMIN D3 DEFICIENCY

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Name of Medication MAGNESIUM

Prophylaxis Yes ☐  
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Mar 2021 01:48:06

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Name of Medication COLLAGEN

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Mar 2021 01:48:06

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Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS OF THE FOOT

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

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

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Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Mar 2021 01:48:06

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Name of Medication NAPROXEN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT FOOT BUNION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Name of Medication MELATONIN

Prophylaxis Yes ☒  
No ☐

Indication GENERAL RESTLESSNESS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

	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)	1 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Name of Medication CBD OIL

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS OF THE FOOT

Dose per administration 1

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

If dose unit is Other, specify DROP

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Name of Medication AMOXICILLIN / CLAVULNATE  
POTASSIUM 875/125

Prophylaxis Yes ☐  
No ☒

Indication POST APPENDICITIS  
(PERFORATED APPENDIX), S/P  
APPENDECTOMY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Name of Medication HYDROCODONE 5/325

Prophylaxis Yes ☐  
No ☒

Indication POST SURGICAL PAIN  
APPENDECTOMY

Dose per administration 1

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

EVERY 4 HOURS PRN

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN IN SIDE POST  
APPENDECTOMY

Dose per administration 200

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	15 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3492178

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 03:57:49

Generated On: 10 Jun 2021 08:00:24

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3492178

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 15 Feb 2021 03:57:49

Generated On: 10 Jun 2021 08:00:24

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
7 JAN 2021	LAPAROSCOPIC APPENDECTOMY	Adverse Event	
7 JAN 2021	CT OF ABDOMEN	Adverse Event	

US3492178

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:00:24

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

US3492178

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:00:24

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 ☐

US3492178

Folder: SAE USA-US101-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

SAEID	USA-US101-2021-MRNA-1273-P301000003
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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3492178

Folder: SAE USA-US101-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

SAEID	USA-US101-2021-MRNA-1273-P301000003
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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/JAN/2021 11:53
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

US3492178

Folder: SAE USA-US101-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

SAEID	USA-US101-2021-MRNA-1273-P301000003
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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/JAN/2021 17:14
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



US3492178

Folder: SAE USA-US101-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

SAEID	USA-US101-2021-MRNA-1273-P301000003
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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	21/JAN/2021 11:25
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

US3492178

Folder: SAE USA-US101-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

SAEID	USA-US101-2021-MRNA-1273-P301000003
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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/FEB/2021 15:33
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

US3492178

Folder: SAE USA-US101-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Mar 2021 01:48:06

Generated On: 10 Jun 2021 08:00:24

SAEID	USA-US101-2021-MRNA-1273-P301000003
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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/MAR/2021 11:06
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

US3492178 (Prod: UIC Project WISH CRS)

**US3492178**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 08:00:24**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'US3492178'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	17 Sep 2020 14:24:33

**US3492178**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:35:07

US3492178

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 14:24:34

**US3492178**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:35:07



**US3492178**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'SCRN'	System	17 Sep 2020 14:35:07

US3492178

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:00:24

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered (b) (6) 1952'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 14:24:35

**US3492178**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:24**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '68'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:35:40

**US3492178**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:24**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'YEARS'	System	17 Sep 2020 14:35:40

**US3492178**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:24**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered '68'	System	17 Sep 2020 14:36:23

**US3492178**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:24**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:35:40

**US3492178**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:24**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:35:40

**US3492178**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:24**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:35:40



**US3492178**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:24**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:35:40

**US3492178**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:24**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:35:40

**US3492178**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:24**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:35:40

**US3492178**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:24**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:35:40

**US3492178**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:24**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 14:35:40

**US3492178**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:24**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:35:40

**US3492178**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:24**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:35:40

**US3492178**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:24**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:35:40



**US3492178**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:00:24**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:36:23

**US3492178**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'Sep 2020'	System	17 Sep 2020 14:36:23

**US3492178**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered '2020'	System	17 Sep 2020 14:36:23

**US3492178**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:00:24**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	17 Sep 2020 14:36:23

**US3492178**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:36:23

**US3492178**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:00:24**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:36:23

**US3492178**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:00:24**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:36:23

**US3492178**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:00:24**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:36:23



**US3492178**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:00:24**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 14:24:34

US3492178

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:24

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'I'	System	17 Sep 2020 14:36:34

US3492178

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:36:34

**US3492178**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 08:00:24**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:09

US3492178

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:00:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:25:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:25:38
Data point term sent to Coder	System	17 Sep 2020 17:24:21
User entered 'HYPERLIPIDEMIA'	(b) (4), (b) (6)	17 Sep 2020 17:23:25

**US3492178**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:25

**US3492178**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:25

**US3492178**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:25



**US3492178**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:25

**US3492178**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:25

**US3492178**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'Jan 2015'	System	17 Sep 2020 17:23:25

**US3492178**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered '2015'	System	17 Sep 2020 17:23:25

**US3492178**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered empty.	System	17 Sep 2020 17:23:25

**US3492178**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered empty.	System	17 Sep 2020 17:23:25

US3492178

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:00:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Hepatic steatosis, LLT: Fatty liver - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:25:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:25:38
Data point term sent to Coder	System	17 Sep 2020 17:24:21
User entered 'FATTY LIVER'	(b) (4), (b) (6)	17 Sep 2020 17:23:41

**US3492178**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:41



**US3492178**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:41

**US3492178**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:41

**US3492178**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:24**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:41

**US3492178**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:41

**US3492178**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'Jan 2015'	System	17 Sep 2020 17:23:41

**US3492178**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered '2015'	System	17 Sep 2020 17:23:41

**US3492178**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'Jan 2018'	System	17 Sep 2020 17:23:41

**US3492178**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered '2018'	System	17 Sep 2020 17:23:41



US3492178

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:00:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Extremity deformities, PT: Foot deformity, LLT: Bunion - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:25:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:25:38
Data point term sent to Coder	System	17 Sep 2020 17:24:22
User entered 'RIGHT FOOT BUNION'	(b) (4), (b) (6)	17 Sep 2020 17:23:56

**US3492178**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:56

**US3492178**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:56

**US3492178**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:56

**US3492178**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:24**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:56

**US3492178**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:23:56

**US3492178**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'Jan 2020'	System	17 Sep 2020 17:23:56

**US3492178**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered '2020'	System	17 Sep 2020 17:23:56



**US3492178**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered empty.	System	17 Sep 2020 17:23:56

**US3492178**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered empty.	System	17 Sep 2020 17:23:56

US3492178

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:00:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless legs syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:25:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:25:39
Data point term sent to Coder	System	17 Sep 2020 17:24:21
User entered 'RESTLESS LEGS SYNDROME'	(b) (4), (b) (6)	17 Sep 2020 17:24:12

**US3492178**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:24:12

**US3492178**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:24:12

**US3492178**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:24:12

**US3492178**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:24**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:24:12

**US3492178**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:24:12



**US3492178**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'Jan 2017'	System	17 Sep 2020 17:24:12

**US3492178**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered '2017'	System	17 Sep 2020 17:24:12

**US3492178**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered empty.	System	17 Sep 2020 17:24:12

**US3492178**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered empty.	System	17 Sep 2020 17:24:12

US3492178

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:00:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:25:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:25:39
Data point term sent to Coder	System	17 Sep 2020 17:25:24
User entered 'SEASONAL ALLERGIES'	(b) (4), (b) (6)	17 Sep 2020 17:24:50

**US3492178**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:24:50

**US3492178**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:24:50

**US3492178**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:24:50



**US3492178**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:24:50

**US3492178**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:24:50

**US3492178**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'Jan 2000'	System	17 Sep 2020 17:24:50

**US3492178**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered '2000'	System	17 Sep 2020 17:24:50

**US3492178**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered empty.	System	17 Sep 2020 17:24:50

**US3492178**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered empty.	System	17 Sep 2020 17:24:50

US3492178

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:00:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D3 deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:25:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:25:52
Data point term sent to Coder	System	17 Sep 2020 17:25:25
User entered 'VITAMIN D3 DEFICIENCY'	(b) (4), (b) (6)	17 Sep 2020 17:25:03

**US3492178**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:25:03



**US3492178**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:25:03

**US3492178**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:25:03

**US3492178**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:25:03

**US3492178**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:25:03

**US3492178**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'Jan 2019'	System	17 Sep 2020 17:25:03

**US3492178**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered '2019'	System	17 Sep 2020 17:25:03

**US3492178**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered empty.	System	17 Sep 2020 17:25:03

**US3492178**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered empty.	System	17 Sep 2020 17:25:03



US3492178

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:00:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:49:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 14:49:21
Data point term sent to Coder	System	12 Oct 2020 14:48:44
User entered 'post-menopausal'	(b) (4), (b) (6)	12 Oct 2020 14:47:51

**US3492178**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'un UNK 2001'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:47:51

**US3492178**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:47:51

**US3492178**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:47:51

**US3492178**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:47:51

**US3492178**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:47:51

**US3492178**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'Jan 2001'	System	12 Oct 2020 14:47:51

**US3492178**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered '2001'	System	12 Oct 2020 14:47:51



**US3492178**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered empty.	System	12 Oct 2020 14:47:51

**US3492178**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered empty.	System	12 Oct 2020 14:47:51

US3492178

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:00:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Foot osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 09:17:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 09:17:44
Data point term sent to Coder	System	28 Jan 2021 18:07:12
User entered 'osteoarthritis of the foot'	(b) (4), (b) (6)	28 Jan 2021 18:07:03

**US3492178**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:07:03

**US3492178**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:07:03

**US3492178**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:07:03

**US3492178**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:24**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:07:03

**US3492178**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:07:03



**US3492178**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'Jan 2018'	System	28 Jan 2021 18:07:03

**US3492178**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered '2018'	System	28 Jan 2021 18:07:03

**US3492178**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered empty.	System	28 Jan 2021 18:07:03

**US3492178**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered empty.	System	28 Jan 2021 18:07:03

**US3492178**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:03

US3492178

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:03

**US3492178**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '09:08'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:03

**US3492178**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered '17 Sep 2020 09:08'	System	17 Sep 2020 17:34:03



**US3492178**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '151.8' cm	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:03
DataPoint set to visible.	System	17 Sep 2020 14:36:34

**US3492178**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '60.3' kg	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:03
DataPoint set to visible.	System	17 Sep 2020 14:36:34

US3492178

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered '26.16820'	System	17 Sep 2020 17:34:03
DataPoint set to visible.	System	17 Sep 2020 14:36:34

**US3492178**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'kg/m2'	System	17 Sep 2020 17:34:03
DataPoint set to visible.	System	17 Sep 2020 14:36:34

US3492178

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:03

US3492178

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User closed query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 13:52:20
Query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' answered with '-----corrected-----' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 19:57:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 19:57:20
User opened query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 18:33:18
User entered 'Other (Other)'	(b) (4), (b) (6)	17 Sep 2020 17:34:03

**US3492178**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:03

**US3492178**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:03



**US3492178**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'bpm'	System	17 Sep 2020 17:34:03

US3492178

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:03

US3492178

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'breaths/min'	System	17 Sep 2020 17:34:03

US3492178

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:03

**US3492178**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'mmHg'	System	17 Sep 2020 17:34:03

**US3492178**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:03

**US3492178**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User entered 'mmHg'	System	17 Sep 2020 17:34:03

**US3492178**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23



US3492178

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23

US3492178

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:33:26

**US3492178**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:24**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:33:26

US3492178

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:00:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:32

US3492178

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:32

US3492178

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:00:24

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:57:55
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:47:58
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 09:26:34
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	17 Sep 2020 17:30:32

US3492178

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:00:24

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:32

US3492178

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:32



**US3492178**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 08:00:24**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:32

**US3492178**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2001'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:32

**US3492178**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 08:00:24**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:32

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36



US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36

**US3492178**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 08:00:24**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36



**US3492178**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 08:00:24**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36

**US3492178**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 08:00:24**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 14:37:36

US3492178

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:21:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:37:36



**US3492178**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:37:28

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:37:28

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:37:28

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'VISIT1'	System	17 Sep 2020 15:37:28

US3492178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 15:00:43

US3492178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '190978'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 15:00:43

US3492178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 15:00:43

US3492178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:24

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:30



US3492178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:24

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:30

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:30

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 08:00:24**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:30

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 08:00:24**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:55:30

US3492178

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:24

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 04:05:11
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	04 Dec 2020 19:16:02
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	04 Dec 2020 19:15:57
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 15:36:15
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:24:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:24:38

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User closed query 'Per CDM: As ND is recorded for Height and Weight, please deselect the units from the unit of measurement box.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:49:39
Query 'Per CDM: As ND is recorded for Height and Weight, please deselect the units from the unit of measurement box.' answered with 'nothing was selected. it is on the dots' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:44:19
User opened query 'Per CDM: As ND is recorded for Height and Weight, please deselect the units from the unit of measurement box.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:15:42
User closed query 'Per CDM: Per CCGs pg 17, HEIGHT and WEIGHT should be recorded as ND. Please update. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 10:30:02
Query 'Per CDM: Per CCGs pg 17, HEIGHT and WEIGHT should be recorded as ND. Please update. ' answered with 'Updated' (Site from DM).	Gizelle Alvarez (b) (4) (b) (4)	29 Sep 2020 17:22:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Gizelle Alvarez (b) (4) (b) (4)	29 Sep 2020 17:22:37
User opened query 'Per CDM: Per CCGs pg 17, HEIGHT and WEIGHT should be recorded as ND. Please update. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 15:52:23
User entered '151.8' cm	(b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 17:22:37
User entered '60.3' kg	(b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User closed query 'Per CDM: As ND is recorded for Height and Weight, please deselect the units from the unit of measurement box.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:49:39
Query 'Per CDM: As ND is recorded for Height and Weight, please deselect the units from the unit of measurement box.' answered with 'nothing was selected. it is on the dots' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:44:19
User opened query 'Per CDM: As ND is recorded for Height and Weight, please deselect the units from the unit of measurement box.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:15:42
User closed query 'Per CDM: Per CCGs pg 17, HEIGHT and WEIGHT should be recorded as ND. Please update. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 10:30:02
Query 'Per CDM: Per CCGs pg 17, HEIGHT and WEIGHT should be recorded as ND. Please update. ' answered with 'Updated' (Site from DM).	Gizelle Alvarez (b) (4) (b) (4)	29 Sep 2020 17:22:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Gizelle Alvarez (b) (4) (b) (4)	29 Sep 2020 17:22:37
User opened query 'Per CDM: Per CCGs pg 17, HEIGHT and WEIGHT should be recorded as ND. Please update. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 15:52:23
User entered '151.8' cm	(b) (4), (b) (6)	17 Sep 2020 17:28:20



US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 17:22:37
User entered '60.3' kg	(b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '09:08'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered '17 Sep 2020 09:08'	System	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20



US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'NOT SPECIFIED'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '61'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'bpm'	System	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '16'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'breaths/min'	System	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '143'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'mmHg'	System	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '81'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20



US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'mmHg'	System	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User closed query 'Per CDM: As ND is recorded for Height and Weight, please deselect the units from the unit of measurement box.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:49:39
Query 'Per CDM: As ND is recorded for Height and Weight, please deselect the units from the unit of measurement box.' answered with 'nothing was selected. it is on the dots' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:44:19
User opened query 'Per CDM: As ND is recorded for Height and Weight, please deselect the units from the unit of measurement box.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:15:42
User closed query 'Per CDM: Per CCGs pg 17, HEIGHT and WEIGHT should be recorded as ND. Please update. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 10:30:02
Query 'Per CDM: Per CCGs pg 17, HEIGHT and WEIGHT should be recorded as ND. Please update. ' answered with 'Updated' (Site from DM).	Gizelle Alvarez (b) (4) (b) (4)	29 Sep 2020 17:22:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Gizelle Alvarez (b) (4) (b) (4)	29 Sep 2020 17:22:37
User opened query 'Per CDM: Per CCGs pg 17, HEIGHT and WEIGHT should be recorded as ND. Please update. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 15:52:23
User entered '151.8' cm	(b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 17:22:37
User entered '60.3' kg	(b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 17:29:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Sep 2020 17:29:57
User entered '10:51' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:29:57
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Sep 2020 17:28:20
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:28:20

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered '17 Sep 2020 10:51'	System	17 Sep 2020 17:29:57
User entered empty.	System	17 Sep 2020 17:28:20



US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'NOT SPECIFIED'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '60'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'bpm'	System	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '18'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'breaths/min'	System	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '155'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20



US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'mmHg'	System	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '86'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:20

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'mmHg'	System	17 Sep 2020 17:28:20

US3492178

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:33:13

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:24**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:33:13

US3492178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:38:11

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:38:11

US3492178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:38:11



**US3492178**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 15:38:11

US3492178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:38:11

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '10:23'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:38:11

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered '17 Sep 2020 10:23'	System	17 Sep 2020 15:38:11

US3492178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:38:11

US3492178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'ONCE'	System	17 Sep 2020 15:38:11

US3492178

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:12



US3492178

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:12

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '09:53'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:12

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered '17 Sep 2020 09:53'	System	17 Sep 2020 17:31:12

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 08:00:24**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:29

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Sep 2020 17:31:29

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:29

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '10:00'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:29

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered '17 Sep 2020 10:00'	System	17 Sep 2020 17:31:29



**US3492178**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Sep 2020 17:31:29

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:29

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:31:29

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered empty.	System	17 Sep 2020 17:31:29

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:54:04

**US3492178**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'I'	System	17 Sep 2020 15:54:04

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:52:07', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '12fde07e-7050-4c68-ab61-55b737c1f5bd'	System	17 Sep 2020 15:52:49
User entered 'Yes (Y)'	System	17 Sep 2020 15:52:49



US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:52:18', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '12fde07e-7050-4c68-ab61-55b737c1f5bd'	System	17 Sep 2020 15:52:49
User entered '98.1'	System	17 Sep 2020 15:52:49

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:52:29', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '12fde07e-7050-4c68-ab61-55b737c1f5bd'	System	17 Sep 2020 15:52:49
User entered 'No (N)'	System	17 Sep 2020 15:52:49

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:52:45', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '12fde07e-7050-4c68-ab61-55b737c1f5bd'	System	17 Sep 2020 15:52:49
User entered '17 Sep 2020 10:52'	System	17 Sep 2020 15:52:49

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Sep 2020 10:43'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Sep 2020 13:13'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T19:57:06', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '36ea26f2-5593-4f36-9df9-ac2386610ed5'	System	18 Sep 2020 00:57:43
User entered 'Yes (Y)'	System	18 Sep 2020 00:57:43

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T19:57:16', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '36ea26f2-5593-4f36-9df9-ac2386610ed5'	System	18 Sep 2020 00:57:43
User entered '97.9'	System	18 Sep 2020 00:57:43



US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T19:57:23', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '36ea26f2-5593-4f36-9df9-ac2386610ed5'	System	18 Sep 2020 00:57:43
User entered 'No (N)'	System	18 Sep 2020 00:57:43

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T19:57:39', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '36ea26f2-5593-4f36-9df9-ac2386610ed5'	System	18 Sep 2020 00:57:43
User entered '17 Sep 2020 19:57'	System	18 Sep 2020 00:57:43

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Sep 2020 14:08'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 2'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:47:09', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'fdcd26fa-7f64-489b-8fad-ea9118528430'	System	19 Sep 2020 00:49:46
User entered 'Yes (Y)'	System	19 Sep 2020 00:49:46

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:47:32', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'fdcd26fa-7f64-489b-8fad-ea9118528430'	System	19 Sep 2020 00:49:46
User entered '98.5'	System	19 Sep 2020 00:49:46

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:47:40', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'fdcd26fa-7f64-489b-8fad-ea9118528430'	System	19 Sep 2020 00:49:46
User entered 'Yes (Y)'	System	19 Sep 2020 00:49:46



US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
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 'participant stated that PRN Naproxen was taken to alleviate pain from bunion to right foot. PRN medication listed in Concomitant medication.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 15:38:27
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).	(b) (4), (b) (6)	16 Nov 2020 19:38:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:49:36', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'fdcd26fa-7f64-489b-8fad-ea9118528430'	System	19 Sep 2020 00:49:46
User entered '1'	System	19 Sep 2020 00:49:46

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:49:36', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'fdcd26fa-7f64-489b-8fad-ea9118528430'	System	19 Sep 2020 00:49:46
User entered '0'	System	19 Sep 2020 00:49:46

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:49:44', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'fdcd26fa-7f64-489b-8fad-ea9118528430'	System	19 Sep 2020 00:49:46
User entered '18 Sep 2020 19:49'	System	19 Sep 2020 00:49:46

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 3'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:36:58', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'b5592293-8c16-45fd-bf7a-0ac3c41eb6a1'	System	20 Sep 2020 00:37:28
User entered 'Yes (Y)'	System	20 Sep 2020 00:37:28

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:37:05', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'b5592293-8c16-45fd-bf7a-0ac3c41eb6a1'	System	20 Sep 2020 00:37:28
User entered '97.1'	System	20 Sep 2020 00:37:28



US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:37:10', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'b5592293-8c16-45fd-bf7a-0ac3c41eb6a1'	System	20 Sep 2020 00:37:28
User entered 'Yes (Y)'	System	20 Sep 2020 00:37:28

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
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 'participant stated that PRN Naproxen was taken to alleviate pain from bunion to right foot. PRN medication listed in Concomitant medication.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 15:38:32
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).	(b) (4), (b) (6)	16 Nov 2020 19:38:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:37:18', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'b5592293-8c16-45fd-bf7a-0ac3c41eb6a1'	System	20 Sep 2020 00:37:28
User entered '1'	System	20 Sep 2020 00:37:28

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:37:18', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'b5592293-8c16-45fd-bf7a-0ac3c41eb6a1'	System	20 Sep 2020 00:37:28
User entered '0'	System	20 Sep 2020 00:37:28

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:37:25', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'b5592293-8c16-45fd-bf7a-0ac3c41eb6a1'	System	20 Sep 2020 00:37:28
User entered '19 Sep 2020 19:37'	System	20 Sep 2020 00:37:28

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 4'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:55:14', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'b285edf7-eef2-4614-926d-dbdfa0b67e93'	System	21 Sep 2020 00:56:30
User entered 'Yes (Y)'	System	21 Sep 2020 00:56:30



US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:55:24', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'b285edf7-eef2-4614-926d-dbdfa0b67e93'	System	21 Sep 2020 00:56:30
User entered '97.7'	System	21 Sep 2020 00:56:30

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:55:28', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'b285edf7-eef2-4614-926d-dbdfa0b67e93'	System	21 Sep 2020 00:56:30
User entered 'No (N)'	System	21 Sep 2020 00:56:30

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:56:24', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'b285edf7-eef2-4614-926d-dbdfa0b67e93'	System	21 Sep 2020 00:56:30
User entered '20 Sep 2020 19:56'	System	21 Sep 2020 00:56:30

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 5'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:19:25', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '29a57775-df99-48ae-84bf-a4aa5f39d753'	System	22 Sep 2020 01:20:37
User entered 'Yes (Y)'	System	22 Sep 2020 01:20:37

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:20:24', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '29a57775-df99-48ae-84bf-a4aa5f39d753'	System	22 Sep 2020 01:20:37
User entered '97.6'	System	22 Sep 2020 01:20:37



US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:20:29', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '29a57775-df99-48ae-84bf-a4aa5f39d753'	System	22 Sep 2020 01:20:37
User entered 'No (N)'	System	22 Sep 2020 01:20:37

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:20:34', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '29a57775-df99-48ae-84bf-a4aa5f39d753'	System	22 Sep 2020 01:20:37
User entered '21 Sep 2020 20:20'	System	22 Sep 2020 01:20:37

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 6'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:31:10', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ad0f8493-b225-4cca-81f1-48b6bcaed701'	System	23 Sep 2020 00:31:31
User entered 'Yes (Y)'	System	23 Sep 2020 00:31:31

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:31:16', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ad0f8493-b225-4cca-81f1-48b6bcaed701'	System	23 Sep 2020 00:31:31
User entered '97.6'	System	23 Sep 2020 00:31:31

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:31:20', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ad0f8493-b225-4cca-81f1-48b6bcaed701'	System	23 Sep 2020 00:31:31
User entered 'No (N)'	System	23 Sep 2020 00:31:31



US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:31:28', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ad0f8493-b225-4cca-81f1-48b6bcaed701'	System	23 Sep 2020 00:31:31
User entered '22 Sep 2020 19:31'	System	23 Sep 2020 00:31:31

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 7'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:21:58', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '273b71d9-1d55-45ef-b5e3-5de9a86d32db'	System	24 Sep 2020 00:22:57
User entered 'Yes (Y)'	System	24 Sep 2020 00:22:57

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:22:39', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '273b71d9-1d55-45ef-b5e3-5de9a86d32db'	System	24 Sep 2020 00:22:57
User entered '97.6'	System	24 Sep 2020 00:22:57

US3492178

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:22:46', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '273b71d9-1d55-45ef-b5e3-5de9a86d32db'	System	24 Sep 2020 00:22:57
User entered 'No (N)'	System	24 Sep 2020 00:22:57

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:22:53', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '273b71d9-1d55-45ef-b5e3-5de9a86d32db'	System	24 Sep 2020 00:22:57
User entered '23 Sep 2020 19:22'	System	24 Sep 2020 00:22:57



**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:52:56', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '839dfa8b-238b-488c-b038-f293ce2d78ae'	System	17 Sep 2020 15:53:48
User entered 'None (1)'	System	17 Sep 2020 15:53:48

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:53:15', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '839dfa8b-238b-488c-b038-f293ce2d78ae'	System	17 Sep 2020 15:53:48
User entered 'No (N)'	System	17 Sep 2020 15:53:48

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:53:24', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '839dfa8b-238b-488c-b038-f293ce2d78ae'	System	17 Sep 2020 15:53:48
User entered 'No (N)'	System	17 Sep 2020 15:53:48

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:53:33', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '839dfa8b-238b-488c-b038-f293ce2d78ae'	System	17 Sep 2020 15:53:48
User entered 'None (1)'	System	17 Sep 2020 15:53:48

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:53:45', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '839dfa8b-238b-488c-b038-f293ce2d78ae'	System	17 Sep 2020 15:53:48
User entered '17 Sep 2020 10:53'	System	17 Sep 2020 15:53:48



**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Sep 2020 10:43'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Sep 2020 13:13'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T19:57:49', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ed2360a1-93a5-42ef-abcb-b5305a9185db'	System	18 Sep 2020 00:59:46
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 00:59:46

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T19:58:55', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ed2360a1-93a5-42ef-abcb-b5305a9185db'	System	18 Sep 2020 00:59:46
User entered 'No (N)'	System	18 Sep 2020 00:59:46

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T19:59:24', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ed2360a1-93a5-42ef-abcb-b5305a9185db'	System	18 Sep 2020 00:59:46
User entered 'No (N)'	System	18 Sep 2020 00:59:46

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T19:59:32', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ed2360a1-93a5-42ef-abcb-b5305a9185db'	System	18 Sep 2020 00:59:46
User entered 'None (1)'	System	18 Sep 2020 00:59:46

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T19:59:42', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ed2360a1-93a5-42ef-abcb-b5305a9185db'	System	18 Sep 2020 00:59:46
User entered '17 Sep 2020 19:59'	System	18 Sep 2020 00:59:46



**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Sep 2020 14:08'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 2'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:50:57', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f4699a91-84ef-4a48-9d81-4b6cb489e9af'	System	19 Sep 2020 00:51:50
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 00:51:50

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:51:01', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f4699a91-84ef-4a48-9d81-4b6cb489e9af'	System	19 Sep 2020 00:51:50
User entered 'No (N)'	System	19 Sep 2020 00:51:50

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:51:05', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f4699a91-84ef-4a48-9d81-4b6cb489e9af'	System	19 Sep 2020 00:51:50
User entered 'No (N)'	System	19 Sep 2020 00:51:50

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:51:16', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f4699a91-84ef-4a48-9d81-4b6cb489e9af'	System	19 Sep 2020 00:51:50
User entered 'None (1)'	System	19 Sep 2020 00:51:50

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:51:47', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f4699a91-84ef-4a48-9d81-4b6cb489e9af'	System	19 Sep 2020 00:51:50
User entered '18 Sep 2020 19:51'	System	19 Sep 2020 00:51:50



**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 3'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:37:40', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'a5a1b4e6-2979-4fa5-a8b7-726524f01e3b'	System	20 Sep 2020 00:38:47
User entered 'None (1)'	System	20 Sep 2020 00:38:47

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:37:49', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'a5a1b4e6-2979-4fa5-a8b7-726524f01e3b'	System	20 Sep 2020 00:38:47
User entered 'No (N)'	System	20 Sep 2020 00:38:47

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:37:52', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'a5a1b4e6-2979-4fa5-a8b7-726524f01e3b'	System	20 Sep 2020 00:38:47
User entered 'No (N)'	System	20 Sep 2020 00:38:47

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:37:59', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'a5a1b4e6-2979-4fa5-a8b7-726524f01e3b'	System	20 Sep 2020 00:38:47
User entered 'None (1)'	System	20 Sep 2020 00:38:47

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:38:45', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'a5a1b4e6-2979-4fa5-a8b7-726524f01e3b'	System	20 Sep 2020 00:38:47
User entered '19 Sep 2020 19:38'	System	20 Sep 2020 00:38:47



**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 4'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:56:36', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5dfb216d-5ada-4cb8-af33-5243e292da7d'	System	21 Sep 2020 00:57:06
User entered 'None (1)'	System	21 Sep 2020 00:57:06

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:56:39', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5dfb216d-5ada-4cb8-af33-5243e292da7d'	System	21 Sep 2020 00:57:06
User entered 'No (N)'	System	21 Sep 2020 00:57:06

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:56:43', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5dfb216d-5ada-4cb8-af33-5243e292da7d'	System	21 Sep 2020 00:57:06
User entered 'No (N)'	System	21 Sep 2020 00:57:06

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:56:53', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5dfb216d-5ada-4cb8-af33-5243e292da7d'	System	21 Sep 2020 00:57:06
User entered 'None (1)'	System	21 Sep 2020 00:57:06

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:57:01', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5dfb216d-5ada-4cb8-af33-5243e292da7d'	System	21 Sep 2020 00:57:06
User entered '20 Sep 2020 19:57'	System	21 Sep 2020 00:57:06



**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 5'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:20:40', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f8eae8e8-9086-4260-b96d-542089c3300b'	System	22 Sep 2020 01:21:35
User entered 'None (1)'	System	22 Sep 2020 01:21:35

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:21:03', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f8eae8e8-9086-4260-b96d-542089c3300b'	System	22 Sep 2020 01:21:35
User entered 'No (N)'	System	22 Sep 2020 01:21:35

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:21:06', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f8eae8e8-9086-4260-b96d-542089c3300b'	System	22 Sep 2020 01:21:35
User entered 'No (N)'	System	22 Sep 2020 01:21:35

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:21:14', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f8eae8e8-9086-4260-b96d-542089c3300b'	System	22 Sep 2020 01:21:35
User entered 'None (1)'	System	22 Sep 2020 01:21:35

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:21:29', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f8eae8e8-9086-4260-b96d-542089c3300b'	System	22 Sep 2020 01:21:35
User entered '21 Sep 2020 20:21'	System	22 Sep 2020 01:21:35



**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 6'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:31:34', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e8c5e725-268e-4a15-860d-26db3fd9ffd7'	System	23 Sep 2020 00:32:17
User entered 'None (1)'	System	23 Sep 2020 00:32:17

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:31:37', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e8c5e725-268e-4a15-860d-26db3fd9ffd7'	System	23 Sep 2020 00:32:17
User entered 'No (N)'	System	23 Sep 2020 00:32:17

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:31:41', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e8c5e725-268e-4a15-860d-26db3fd9ffd7'	System	23 Sep 2020 00:32:17
User entered 'No (N)'	System	23 Sep 2020 00:32:17

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:32:03', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e8c5e725-268e-4a15-860d-26db3fd9ffd7'	System	23 Sep 2020 00:32:17
User entered 'None (1)'	System	23 Sep 2020 00:32:17

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:32:14', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e8c5e725-268e-4a15-860d-26db3fd9ffd7'	System	23 Sep 2020 00:32:17
User entered '22 Sep 2020 19:32'	System	23 Sep 2020 00:32:17



**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 7'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:23:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f47b05b4-2b70-40fc-a8b0-1c9c979d6cb9'	System	24 Sep 2020 00:23:34
User entered 'None (1)'	System	24 Sep 2020 00:23:34

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:23:04', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f47b05b4-2b70-40fc-a8b0-1c9c979d6cb9'	System	24 Sep 2020 00:23:34
User entered 'No (N)'	System	24 Sep 2020 00:23:34

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:23:09', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f47b05b4-2b70-40fc-a8b0-1c9c979d6cb9'	System	24 Sep 2020 00:23:34
User entered 'No (N)'	System	24 Sep 2020 00:23:34

US3492178

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:23:20', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f47b05b4-2b70-40fc-a8b0-1c9c979d6cb9'	System	24 Sep 2020 00:23:34
User entered 'None (1)'	System	24 Sep 2020 00:23:34

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:23:30', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'f47b05b4-2b70-40fc-a8b0-1c9c979d6cb9'	System	24 Sep 2020 00:23:34
User entered '23 Sep 2020 19:23'	System	24 Sep 2020 00:23:34



**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:54:06', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e14588b0-40a3-4a81-8f61-e475e10da21c'	System	17 Sep 2020 15:55:42
User entered 'None (0)'	System	17 Sep 2020 15:55:42

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:54:19', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e14588b0-40a3-4a81-8f61-e475e10da21c'	System	17 Sep 2020 15:55:42
User entered 'None (0)'	System	17 Sep 2020 15:55:42

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:54:30', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e14588b0-40a3-4a81-8f61-e475e10da21c'	System	17 Sep 2020 15:55:42
User entered 'None (0)'	System	17 Sep 2020 15:55:42

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:54:43', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e14588b0-40a3-4a81-8f61-e475e10da21c'	System	17 Sep 2020 15:55:42
User entered 'None (0)'	System	17 Sep 2020 15:55:42

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:55:03', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e14588b0-40a3-4a81-8f61-e475e10da21c'	System	17 Sep 2020 15:55:42
User entered 'None (0)'	System	17 Sep 2020 15:55:42



US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:55:09', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e14588b0-40a3-4a81-8f61-e475e10da21c'	System	17 Sep 2020 15:55:42
User entered 'None (0)'	System	17 Sep 2020 15:55:42

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:55:23', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e14588b0-40a3-4a81-8f61-e475e10da21c'	System	17 Sep 2020 15:55:42
User entered 'No (N)'	System	17 Sep 2020 15:55:42

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T10:55:39', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e14588b0-40a3-4a81-8f61-e475e10da21c'	System	17 Sep 2020 15:55:42
User entered '17 Sep 2020 10:55'	System	17 Sep 2020 15:55:42

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Sep 2020 10:43'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Sep 2020 13:13'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T19:59:51', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '383ca455-9f42-47af-9570-b1e0004024fa'	System	18 Sep 2020 01:00:51
User entered 'None (0)'	System	18 Sep 2020 01:00:51

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T19:59:56', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '383ca455-9f42-47af-9570-b1e0004024fa'	System	18 Sep 2020 01:00:51
User entered 'None (0)'	System	18 Sep 2020 01:00:51



US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T20:00:02', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '383ca455-9f42-47af-9570-b1e0004024fa'	System	18 Sep 2020 01:00:51
User entered 'None (0)'	System	18 Sep 2020 01:00:51

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T20:00:06', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '383ca455-9f42-47af-9570-b1e0004024fa'	System	18 Sep 2020 01:00:51
User entered 'None (0)'	System	18 Sep 2020 01:00:51

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T20:00:21', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '383ca455-9f42-47af-9570-b1e0004024fa' User entered 'None (0)'	System	18 Sep 2020 01:00:51
	System	18 Sep 2020 01:00:51

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T20:00:25', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '383ca455-9f42-47af-9570-b1e0004024fa'	System	18 Sep 2020 01:00:51
User entered 'None (0)'	System	18 Sep 2020 01:00:51

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T20:00:33', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '383ca455-9f42-47af-9570-b1e0004024fa'	System	18 Sep 2020 01:00:51
User entered 'No (N)'	System	18 Sep 2020 01:00:51

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-17T20:00:47', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '383ca455-9f42-47af-9570-b1e0004024fa'	System	18 Sep 2020 01:00:51
User entered '17 Sep 2020 20:00'	System	18 Sep 2020 01:00:51

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Sep 2020 14:08'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 15:38:11



US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 2'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:52:04', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '18a47e37-c262-4e12-aa3f-6bf0d28ca857'	System	19 Sep 2020 01:00:08
User entered 'None (0)'	System	19 Sep 2020 01:00:08

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:52:29', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '18a47e37-c262-4e12-aa3f-6bf0d28ca857'	System	19 Sep 2020 01:00:08
User entered 'None (0)'	System	19 Sep 2020 01:00:08

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:58:49', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '18a47e37-c262-4e12-aa3f-6bf0d28ca857'	System	19 Sep 2020 01:00:08
User entered 'None (0)'	System	19 Sep 2020 01:00:08

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:59:14', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '18a47e37-c262-4e12-aa3f-6bf0d28ca857'	System	19 Sep 2020 01:00:08
User entered 'None (0)'	System	19 Sep 2020 01:00:08

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:59:37', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '18a47e37-c262-4e12-aa3f-6bf0d28ca857'	System	19 Sep 2020 01:00:08
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	19 Sep 2020 01:00:08

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:59:40', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '18a47e37-c262-4e12-aa3f-6bf0d28ca857'	System	19 Sep 2020 01:00:08
User entered 'None (0)'	System	19 Sep 2020 01:00:08

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T19:59:49', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '18a47e37-c262-4e12-aa3f-6bf0d28ca857'	System	19 Sep 2020 01:00:08
User entered 'No (N)'	System	19 Sep 2020 01:00:08



**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-18T20:00:05', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '18a47e37-c262-4e12-aa3f-6bf0d28ca857'	System	19 Sep 2020 01:00:08
User entered '18 Sep 2020 20:00'	System	19 Sep 2020 01:00:08

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 3'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:38:51', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '58c73508-0b76-4c3a-b036-9c33ed0fd69b'	System	20 Sep 2020 00:39:43
User entered 'None (0)'	System	20 Sep 2020 00:39:43

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:38:56', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '58c73508-0b76-4c3a-b036-9c33ed0fd69b'	System	20 Sep 2020 00:39:43
User entered 'None (0)'	System	20 Sep 2020 00:39:43

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:39:03', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '58c73508-0b76-4c3a-b036-9c33ed0fd69b' User entered 'None (0)'	System	20 Sep 2020 00:39:43
	System	20 Sep 2020 00:39:43

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:39:21', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '58c73508-0b76-4c3a-b036-9c33ed0fd69b'	System	20 Sep 2020 00:39:43
User entered 'None (0)'	System	20 Sep 2020 00:39:43



US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:39:25', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '58c73508-0b76-4c3a-b036-9c33ed0fd69b'	System	20 Sep 2020 00:39:43
User entered 'None (0)'	System	20 Sep 2020 00:39:43

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:39:28', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '58c73508-0b76-4c3a-b036-9c33ed0fd69b'	System	20 Sep 2020 00:39:43
User entered 'None (0)'	System	20 Sep 2020 00:39:43

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:39:31', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '58c73508-0b76-4c3a-b036-9c33ed0fd69b'	System	20 Sep 2020 00:39:43
User entered 'No (N)'	System	20 Sep 2020 00:39:43

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-19T19:39:41', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '58c73508-0b76-4c3a-b036-9c33ed0fd69b'	System	20 Sep 2020 00:39:43
User entered '19 Sep 2020 19:39'	System	20 Sep 2020 00:39:43

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 4'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:57:55', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'c9c2fcc1-5d62-4a13-bb16-fc0619cc57a1'	System	21 Sep 2020 00:58:37
User entered 'None (0)'	System	21 Sep 2020 00:58:37



US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:58:06', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'c9c2fcc1-5d62-4a13-bb16-fc0619cc57a1'	System	21 Sep 2020 00:58:37
User entered 'None (0)'	System	21 Sep 2020 00:58:37

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:58:10', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'c9c2fcc1-5d62-4a13-bb16-fc0619cc57a1'	System	21 Sep 2020 00:58:37
User entered 'None (0)'	System	21 Sep 2020 00:58:37

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:58:13', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'c9c2fcc1-5d62-4a13-bb16-fc0619cc57a1' User entered 'None (0)'	System	21 Sep 2020 00:58:37
	System	21 Sep 2020 00:58:37

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:58:16', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'c9c2fcc1-5d62-4a13-bb16-fc0619cc57a1'	System	21 Sep 2020 00:58:37
User entered 'None (0)'	System	21 Sep 2020 00:58:37

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:58:19', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'c9c2fcc1-5d62-4a13-bb16-fc0619cc57a1'	System	21 Sep 2020 00:58:37
User entered 'None (0)'	System	21 Sep 2020 00:58:37

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:58:26', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'c9c2fcc1-5d62-4a13-bb16-fc0619cc57a1'	System	21 Sep 2020 00:58:37
User entered 'No (N)'	System	21 Sep 2020 00:58:37

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-20T19:58:33', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'c9c2fcc1-5d62-4a13-bb16-fc0619cc57a1'	System	21 Sep 2020 00:58:37
User entered '20 Sep 2020 19:58'	System	21 Sep 2020 00:58:37

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 15:38:11



**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 5'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:21:37', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '2e5267e1-68f9-4b9f-a78b-851605fecaa6'	System	22 Sep 2020 01:23:53
User entered 'No interference with activity (1)'	System	22 Sep 2020 01:23:53

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:21:46', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '2e5267e1-68f9-4b9f-a78b-851605fecaa6'	System	22 Sep 2020 01:23:53
User entered 'None (0)'	System	22 Sep 2020 01:23:53

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:21:53', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '2e5267e1-68f9-4b9f-a78b-851605fecaa6'	System	22 Sep 2020 01:23:53
User entered 'No interference with activity (1)'	System	22 Sep 2020 01:23:53

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:22:03', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '2e5267e1-68f9-4b9f-a78b-851605fecaa6'	System	22 Sep 2020 01:23:53
User entered 'None (0)'	System	22 Sep 2020 01:23:53

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:22:53', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '2e5267e1-68f9-4b9f-a78b-851605fecaa6'	System	22 Sep 2020 01:23:53
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	22 Sep 2020 01:23:53

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:22:56', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '2e5267e1-68f9-4b9f-a78b-851605fecaa6'	System	22 Sep 2020 01:23:53
User entered 'None (0)'	System	22 Sep 2020 01:23:53



US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:23:06', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '2e5267e1-68f9-4b9f-a78b-851605fecaa6'	System	22 Sep 2020 01:23:53
User entered 'No (N)'	System	22 Sep 2020 01:23:53

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-21T20:23:49', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '2e5267e1-68f9-4b9f-a78b-851605fecaa6'	System	22 Sep 2020 01:23:53
User entered '21 Sep 2020 20:23'	System	22 Sep 2020 01:23:53

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 6'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:32:21', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5982b41f-8bca-4ab2-a33e-c44b36333282'	System	23 Sep 2020 00:33:31
User entered 'No interference with activity (1)'	System	23 Sep 2020 00:33:31

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:32:25', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5982b41f-8bca-4ab2-a33e-c44b36333282'	System	23 Sep 2020 00:33:31
User entered 'No interference with activity (1)'	System	23 Sep 2020 00:33:31

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:32:48', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5982b41f-8bca-4ab2-a33e-c44b36333282'	System	23 Sep 2020 00:33:31
User entered 'No interference with activity (1)'	System	23 Sep 2020 00:33:31



US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:32:56', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5982b41f-8bca-4ab2-a33e-c44b36333282'	System	23 Sep 2020 00:33:31
User entered 'None (0)'	System	23 Sep 2020 00:33:31

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:32:59', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5982b41f-8bca-4ab2-a33e-c44b36333282'	System	23 Sep 2020 00:33:31
User entered 'None (0)'	System	23 Sep 2020 00:33:31

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:33:01', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5982b41f-8bca-4ab2-a33e-c44b36333282'	System	23 Sep 2020 00:33:31
User entered 'None (0)'	System	23 Sep 2020 00:33:31

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:33:06', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5982b41f-8bca-4ab2-a33e-c44b36333282'	System	23 Sep 2020 00:33:31
User entered 'No (N)'	System	23 Sep 2020 00:33:31

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-22T19:33:28', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5982b41f-8bca-4ab2-a33e-c44b36333282'	System	23 Sep 2020 00:33:31
User entered '22 Sep 2020 19:33'	System	23 Sep 2020 00:33:31

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 7'	System	17 Sep 2020 15:38:11



US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:23:37', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '17009bf5-49ae-4b53-9129-dd889f4d9199'	System	24 Sep 2020 00:24:18
User entered 'None (0)'	System	24 Sep 2020 00:24:18

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:23:45', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '17009bf5-49ae-4b53-9129-dd889f4d9199'	System	24 Sep 2020 00:24:18
User entered 'None (0)'	System	24 Sep 2020 00:24:18

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:23:49', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '17009bf5-49ae-4b53-9129-dd889f4d9199'	System	24 Sep 2020 00:24:18
User entered 'None (0)'	System	24 Sep 2020 00:24:18

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:23:53', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '17009bf5-49ae-4b53-9129-dd889f4d9199'	System	24 Sep 2020 00:24:18
User entered 'None (0)'	System	24 Sep 2020 00:24:18

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:23:56', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '17009bf5-49ae-4b53-9129-dd889f4d9199'	System	24 Sep 2020 00:24:18
User entered 'None (0)'	System	24 Sep 2020 00:24:18

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:23:59', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '17009bf5-49ae-4b53-9129-dd889f4d9199'	System	24 Sep 2020 00:24:18
User entered 'None (0)'	System	24 Sep 2020 00:24:18

US3492178

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:24:08', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '17009bf5-49ae-4b53-9129-dd889f4d9199'	System	24 Sep 2020 00:24:18
User entered 'No (N)'	System	24 Sep 2020 00:24:18

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-09-23T19:24:16', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '17009bf5-49ae-4b53-9129-dd889f4d9199'	System	24 Sep 2020 00:24:18
User entered '23 Sep 2020 19:24'	System	24 Sep 2020 00:24:18



**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 15:38:11

**US3492178**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	24 Sep 2020 15:58:06

**US3492178**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '24 Sep 2020'	Addis Mekonnen (b) (4)	24 Sep 2020 15:58:06

**US3492178**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Addis Mekonnen (b) (4)	24 Sep 2020 15:58:06

US3492178

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	Addis Mekonnen (b) (4)	24 Sep 2020 15:58:06

US3492178

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) Addis Mekonnen (b) (4)	24 Sep 2020 15:58:10

**US3492178**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'I'	System	24 Sep 2020 15:58:10



US3492178

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	Elena Llinas (b) (4)	01 Oct 2020 20:11:27

**US3492178**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '1 Oct 2020'	Elena Llinas (b) (4)	01 Oct 2020 20:11:27

US3492178

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4)	01 Oct 2020 20:11:27

**US3492178**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	Elena Llinas (b) (4)	01 Oct 2020 20:11:27

US3492178

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	Elena Llinas (b) (4)	01 Oct 2020 20:11:33

**US3492178**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'I'	System	01 Oct 2020 20:11:33

**US3492178**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:12:37

**US3492178**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:12:37



**US3492178**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:12:37

**US3492178**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:12:37

US3492178

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:12:40

**US3492178**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'I'	System	09 Oct 2020 16:12:40

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:15:04

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:15:04

US3492178

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:15:04

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'VISIT2'	System	15 Oct 2020 13:15:04



**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '08:12'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered '15 Oct 2020 08:12'	System	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'not specified'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30



US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '62'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'bpm'	System	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '20'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'breaths/min'	System	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '125'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'mmHg'	System	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '84'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'mmHg'	System	16 Oct 2020 22:01:30



US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '10:10'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered '15 Oct 2020 10:10'	System	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'not specified'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30



US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '63'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'bpm'	System	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '20'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'breaths/min'	System	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '127'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'mmHg'	System	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '86'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:30

US3492178

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'mmHg'	System	16 Oct 2020 22:01:30



**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:24**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:42

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:24**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:01:42

US3492178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:49:22

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:49:22

US3492178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:49:22

US3492178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 14:49:22

US3492178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:49:22

US3492178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '09:40'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:49:22



**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered '15 Oct 2020 09:40'	System	15 Oct 2020 14:49:22

US3492178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:49:22

US3492178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'ONCE'	System	15 Oct 2020 14:49:22

US3492178

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 14:49:22

US3492178

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:02:09

US3492178

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:02:09

US3492178

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '08:36' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 22:02:17
User entered '08:43'	(b) (4), (b) (6)	16 Oct 2020 22:02:09

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered '15 Oct 2020 08:36'	System	16 Oct 2020 22:02:17
User entered '15 Oct 2020 08:43'	System	16 Oct 2020 22:02:09



**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 08:00:24**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:02:36

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Oct 2020 22:02:36

US3492178

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:00:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:02:36

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '08:43'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:02:36

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered '15 Oct 2020 08:43'	System	16 Oct 2020 22:02:36

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Oct 2020 22:02:36

US3492178

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:00:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:02:36

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 22:02:36



**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered empty.	System	16 Oct 2020 22:02:36

US3492178

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 14:48:49

**US3492178**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'I'	System	15 Oct 2020 14:48:49

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:01:16', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e7c93d30-6abb-421c-ba42-9e175087de3d'	System	15 Oct 2020 15:01:39
User entered 'Yes (Y)'	System	15 Oct 2020 15:01:39

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:01:23', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e7c93d30-6abb-421c-ba42-9e175087de3d' User entered '98.3'	System	15 Oct 2020 15:01:39
	System	15 Oct 2020 15:01:39

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:01:28', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e7c93d30-6abb-421c-ba42-9e175087de3d'	System	15 Oct 2020 15:01:39
User entered 'No (N)'	System	15 Oct 2020 15:01:39

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:01:33', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e7c93d30-6abb-421c-ba42-9e175087de3d' User entered '15 Oct 2020 10:01'	System	15 Oct 2020 15:01:39
	System	15 Oct 2020 15:01:39



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '15 Oct 2020 10:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '15 Oct 2020 12:30'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:07:49', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '36eda6d7-f540-4ecf-a016-31d4d4a23f37'	System	16 Oct 2020 01:08:11
User entered 'Yes (Y)'	System	16 Oct 2020 01:08:11

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:07:55', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '36eda6d7-f540-4ecf-a016-31d4d4a23f37'	System	16 Oct 2020 01:08:11
User entered '96.8'	System	16 Oct 2020 01:08:11

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:07:59', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '36eda6d7-f540-4ecf-a016-31d4d4a23f37'	System	16 Oct 2020 01:08:11
User entered 'No (N)'	System	16 Oct 2020 01:08:11

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:08:05', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '36eda6d7-f540-4ecf-a016-31d4d4a23f37'	System	16 Oct 2020 01:08:11
User entered '15 Oct 2020 20:08'	System	16 Oct 2020 01:08:11

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '15 Oct 2020 13:25'	System	15 Oct 2020 14:49:22



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 2'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:11:56', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'b28fb9fe-e79e-4a29-bd0e-e66e7eb121da'	System	17 Oct 2020 00:12:14
User entered 'Yes (Y)'	System	17 Oct 2020 00:12:14

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:12:03', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'b28fb9fe-e79e-4a29-bd0e-e66e7eb121da'	System	17 Oct 2020 00:12:14
User entered '97.9'	System	17 Oct 2020 00:12:14

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:12:07', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'b28fb9fe-e79e-4a29-bd0e-e66e7eb121da'	System	17 Oct 2020 00:12:14
User entered 'No (N)'	System	17 Oct 2020 00:12:14

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:12:12', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'b28fb9fe-e79e-4a29-bd0e-e66e7eb121da'	System	17 Oct 2020 00:12:14
User entered '16 Oct 2020 19:12'	System	17 Oct 2020 00:12:14

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 14:49:22



US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 3'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:05:11', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '55a73035-5b72-479f-b738-2169af722c0b'	System	18 Oct 2020 01:05:31
User entered 'Yes (Y)'	System	18 Oct 2020 01:05:31

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:05:19', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '55a73035-5b72-479f-b738-2169af722c0b' User entered '97.1'	System	18 Oct 2020 01:05:31
	System	18 Oct 2020 01:05:31

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:05:23', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '55a73035-5b72-479f-b738-2169af722c0b'	System	18 Oct 2020 01:05:31
User entered 'No (N)'	System	18 Oct 2020 01:05:31

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:05:28', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '55a73035-5b72-479f-b738-2169af722c0b'	System	18 Oct 2020 01:05:31
User entered '17 Oct 2020 20:05'	System	18 Oct 2020 01:05:31

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 4'	System	15 Oct 2020 14:49:22



US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:50:52', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1628dffe-b6f7-472f-8510-43152532145f'	System	19 Oct 2020 00:51:08
User entered 'Yes (Y)'	System	19 Oct 2020 00:51:08

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:50:59', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1628dffe-b6f7-472f-8510-43152532145f' User entered '97.7'	System	19 Oct 2020 00:51:08
	System	19 Oct 2020 00:51:08

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:51:02', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1628dffe-b6f7-472f-8510-43152532145f'	System	19 Oct 2020 00:51:08
User entered 'No (N)'	System	19 Oct 2020 00:51:08

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:51:06', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1628dffe-b6f7-472f-8510-43152532145f'	System	19 Oct 2020 00:51:08
User entered '18 Oct 2020 19:51'	System	19 Oct 2020 00:51:08

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 5'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:52:03', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1303b917-97dc-45c9-aac7-17635fe6c9ee'	System	19 Oct 2020 23:52:20
User entered 'Yes (Y)'	System	19 Oct 2020 23:52:20



US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:52:08', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1303b917-97dc-45c9-aac7-17635fe6c9ee'	System	19 Oct 2020 23:52:20
User entered '97.2'	System	19 Oct 2020 23:52:20

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:52:12', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1303b917-97dc-45c9-aac7-17635fe6c9ee'	System	19 Oct 2020 23:52:20
User entered 'No (N)'	System	19 Oct 2020 23:52:20

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:52:16', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1303b917-97dc-45c9-aac7-17635fe6c9ee'	System	19 Oct 2020 23:52:20
User entered '19 Oct 2020 18:52'	System	19 Oct 2020 23:52:20

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 6'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:03:19', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '2101f89a-33fe-465d-ba14-73f399ae2cbd'	System	21 Oct 2020 00:03:40
User entered 'Yes (Y)'	System	21 Oct 2020 00:03:40

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:03:25', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '2101f89a-33fe-465d-ba14-73f399ae2cbd'	System	21 Oct 2020 00:03:40
User entered '97.4'	System	21 Oct 2020 00:03:40



US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:03:29', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '2101f89a-33fe-465d-ba14-73f399ae2cbd'	System	21 Oct 2020 00:03:40
User entered 'No (N)'	System	21 Oct 2020 00:03:40

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:03:34', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '2101f89a-33fe-465d-ba14-73f399ae2cbd'	System	21 Oct 2020 00:03:40
User entered '20 Oct 2020 19:03'	System	21 Oct 2020 00:03:40

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 7'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:29:39', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'a706b584-c5e1-4274-aff3-c6575fed7179'	System	22 Oct 2020 00:30:23
User entered 'Yes (Y)'	System	22 Oct 2020 00:30:23

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:29:44', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'a706b584-c5e1-4274-aff3-c6575fed7179'	System	22 Oct 2020 00:30:23
User entered '96.8'	System	22 Oct 2020 00:30:23

US3492178

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:30:10', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'a706b584-c5e1-4274-aff3-c6575fed7179'	System	22 Oct 2020 00:30:23
User entered 'No (N)'	System	22 Oct 2020 00:30:23



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:30:21', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'a706b584-c5e1-4274-aff3-c6575fed7179'	System	22 Oct 2020 00:30:23
User entered '21 Oct 2020 19:30'	System	22 Oct 2020 00:30:23

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:01:43', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '3f09d514-d826-480c-ad89-e5aa88b705bd'	System	15 Oct 2020 15:02:39
User entered 'None (1)'	System	15 Oct 2020 15:02:39

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:02:05', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '3f09d514-d826-480c-ad89-e5aa88b705bd'	System	15 Oct 2020 15:02:39
User entered 'No (N)'	System	15 Oct 2020 15:02:39

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:02:18', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '3f09d514-d826-480c-ad89-e5aa88b705bd'	System	15 Oct 2020 15:02:39
User entered 'No (N)'	System	15 Oct 2020 15:02:39

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:02:23', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '3f09d514-d826-480c-ad89-e5aa88b705bd'	System	15 Oct 2020 15:02:39
User entered 'None (1)'	System	15 Oct 2020 15:02:39



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:02:33', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '3f09d514-d826-480c-ad89-e5aa88b705bd'	System	15 Oct 2020 15:02:39
User entered '15 Oct 2020 10:02'	System	15 Oct 2020 15:02:39

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '15 Oct 2020 10:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '15 Oct 2020 12:30'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:08:15', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ea6b1df8-c2eb-4784-a416-e6d404d1f110'	System	16 Oct 2020 01:09:43
User entered 'None (1)'	System	16 Oct 2020 01:09:43

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:09:19', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ea6b1df8-c2eb-4784-a416-e6d404d1f110'	System	16 Oct 2020 01:09:43
User entered 'No (N)'	System	16 Oct 2020 01:09:43

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:09:27', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ea6b1df8-c2eb-4784-a416-e6d404d1f110'	System	16 Oct 2020 01:09:43
User entered 'No (N)'	System	16 Oct 2020 01:09:43

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:09:34', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ea6b1df8-c2eb-4784-a416-e6d404d1f110'	System	16 Oct 2020 01:09:43
User entered 'None (1)'	System	16 Oct 2020 01:09:43



US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:09:40', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ea6b1df8-c2eb-4784-a416-e6d404d1f110'	System	16 Oct 2020 01:09:43
User entered '15 Oct 2020 20:09'	System	16 Oct 2020 01:09:43

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '15 Oct 2020 13:25'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 2'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:12:18', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '8ed2f77b-f437-4c4f-b239-9a2d683bb92f'	System	17 Oct 2020 00:13:29
User entered 'None (1)'	System	17 Oct 2020 00:13:29

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:13:12', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '8ed2f77b-f437-4c4f-b239-9a2d683bb92f'	System	17 Oct 2020 00:13:29
User entered 'No (N)'	System	17 Oct 2020 00:13:29

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:13:15', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '8ed2f77b-f437-4c4f-b239-9a2d683bb92f'	System	17 Oct 2020 00:13:29
User entered 'No (N)'	System	17 Oct 2020 00:13:29

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:13:21', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '8ed2f77b-f437-4c4f-b239-9a2d683bb92f'	System	17 Oct 2020 00:13:29
User entered 'None (1)'	System	17 Oct 2020 00:13:29



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:13:26', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '8ed2f77b-f437-4c4f-b239-9a2d683bb92f'	System	17 Oct 2020 00:13:29
User entered '16 Oct 2020 19:13'	System	17 Oct 2020 00:13:29

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 3'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:05:37', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd9a796ee-7b92-41c1-b461-eaeba7e3d2d9'	System	18 Oct 2020 01:05:59
User entered 'None (1)'	System	18 Oct 2020 01:05:59

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:05:40', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd9a796ee-7b92-41c1-b461-eaeba7e3d2d9'	System	18 Oct 2020 01:05:59
User entered 'No (N)'	System	18 Oct 2020 01:05:59

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:05:44', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd9a796ee-7b92-41c1-b461-eaeba7e3d2d9'	System	18 Oct 2020 01:05:59
User entered 'No (N)'	System	18 Oct 2020 01:05:59

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:05:47', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd9a796ee-7b92-41c1-b461-eaeba7e3d2d9'	System	18 Oct 2020 01:05:59
User entered 'None (1)'	System	18 Oct 2020 01:05:59



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:05:55', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd9a796ee-7b92-41c1-b461-eaeba7e3d2d9'	System	18 Oct 2020 01:05:59
User entered '17 Oct 2020 20:05'	System	18 Oct 2020 01:05:59

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 4'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:51:11', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '42afe805-bd06-42f1-9861-619cbf166ce5'	System	19 Oct 2020 00:51:42
User entered 'None (1)'	System	19 Oct 2020 00:51:42

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:51:16', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '42afe805-bd06-42f1-9861-619cbf166ce5'	System	19 Oct 2020 00:51:42
User entered 'No (N)'	System	19 Oct 2020 00:51:42

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:51:20', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '42afe805-bd06-42f1-9861-619cbf166ce5'	System	19 Oct 2020 00:51:42
User entered 'No (N)'	System	19 Oct 2020 00:51:42

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:51:28', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '42afe805-bd06-42f1-9861-619cbf166ce5'	System	19 Oct 2020 00:51:42
User entered 'None (1)'	System	19 Oct 2020 00:51:42



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:51:38', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '42afe805-bd06-42f1-9861-619cbf166ce5'	System	19 Oct 2020 00:51:42
User entered '18 Oct 2020 19:51'	System	19 Oct 2020 00:51:42

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 5'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:52:22', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'afbb15e2-ef0a-426c-bf0c-78647f1855f3'	System	19 Oct 2020 23:52:44
User entered 'None (1)'	System	19 Oct 2020 23:52:44

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:52:25', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'afbb15e2-ef0a-426c-bf0c-78647f1855f3'	System	19 Oct 2020 23:52:44
User entered 'No (N)'	System	19 Oct 2020 23:52:44

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:52:32', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'afbb15e2-ef0a-426c-bf0c-78647f1855f3'	System	19 Oct 2020 23:52:44
User entered 'No (N)'	System	19 Oct 2020 23:52:44

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:52:35', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'afbb15e2-ef0a-426c-bf0c-78647f1855f3'	System	19 Oct 2020 23:52:44
User entered 'None (1)'	System	19 Oct 2020 23:52:44



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:52:40', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'afbb15e2-ef0a-426c-bf0c-78647f1855f3'	System	19 Oct 2020 23:52:44
User entered '19 Oct 2020 18:52'	System	19 Oct 2020 23:52:44

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 6'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:03:41', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd324e500-f6bd-4a5b-81fd-7747317cdbba'	System	21 Oct 2020 00:04:06
User entered 'None (1)'	System	21 Oct 2020 00:04:06

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:03:45', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd324e500-f6bd-4a5b-81fd-7747317cdbba'	System	21 Oct 2020 00:04:06
User entered 'No (N)'	System	21 Oct 2020 00:04:06

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:03:50', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd324e500-f6bd-4a5b-81fd-7747317cdbba'	System	21 Oct 2020 00:04:06
User entered 'No (N)'	System	21 Oct 2020 00:04:06

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:03:56', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd324e500-f6bd-4a5b-81fd-7747317cdbba'	System	21 Oct 2020 00:04:06
User entered 'None (1)'	System	21 Oct 2020 00:04:06



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:04:01', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd324e500-f6bd-4a5b-81fd-7747317cdbba'	System	21 Oct 2020 00:04:06
User entered '20 Oct 2020 19:04'	System	21 Oct 2020 00:04:06

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 7'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:30:57', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '96344192-8960-4b84-a9f9-ec7ff5600b85'	System	22 Oct 2020 00:31:20
User entered 'None (1)'	System	22 Oct 2020 00:31:20

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:31:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '96344192-8960-4b84-a9f9-ec7ff5600b85'	System	22 Oct 2020 00:31:20
User entered 'No (N)'	System	22 Oct 2020 00:31:20

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:31:06', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '96344192-8960-4b84-a9f9-ec7ff5600b85'	System	22 Oct 2020 00:31:20
User entered 'No (N)'	System	22 Oct 2020 00:31:20

US3492178

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:31:11', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '96344192-8960-4b84-a9f9-ec7ff5600b85'	System	22 Oct 2020 00:31:20
User entered 'None (1)'	System	22 Oct 2020 00:31:20



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:31:16', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '96344192-8960-4b84-a9f9-ec7ff5600b85'	System	22 Oct 2020 00:31:20
User entered '21 Oct 2020 19:31'	System	22 Oct 2020 00:31:20

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:02:39', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e66d19a0-1d07-473f-9c70-70698abe43d6'	System	15 Oct 2020 15:03:25
User entered 'None (0)'	System	15 Oct 2020 15:03:25

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:02:43', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e66d19a0-1d07-473f-9c70-70698abe43d6'	System	15 Oct 2020 15:03:25
User entered 'None (0)'	System	15 Oct 2020 15:03:25

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:02:49', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e66d19a0-1d07-473f-9c70-70698abe43d6' User entered 'None (0)'	System	15 Oct 2020 15:03:25
	System	15 Oct 2020 15:03:25

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:02:52', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e66d19a0-1d07-473f-9c70-70698abe43d6'	System	15 Oct 2020 15:03:25
User entered 'None (0)'	System	15 Oct 2020 15:03:25



US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:02:58', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e66d19a0-1d07-473f-9c70-70698abe43d6'	System	15 Oct 2020 15:03:25
User entered 'None (0)'	System	15 Oct 2020 15:03:25

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:03:02', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e66d19a0-1d07-473f-9c70-70698abe43d6'	System	15 Oct 2020 15:03:25
User entered 'None (0)'	System	15 Oct 2020 15:03:25

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:03:14', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e66d19a0-1d07-473f-9c70-70698abe43d6'	System	15 Oct 2020 15:03:25
User entered 'No (N)'	System	15 Oct 2020 15:03:25

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T10:03:20', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e66d19a0-1d07-473f-9c70-70698abe43d6'	System	15 Oct 2020 15:03:25
User entered '15 Oct 2020 10:03'	System	15 Oct 2020 15:03:25

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '15 Oct 2020 10:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '15 Oct 2020 12:30'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:09:47', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1a04395d-fd2a-4a2f-b012-f63394fc7f5b'	System	16 Oct 2020 01:10:29
User entered 'None (0)'	System	16 Oct 2020 01:10:29



US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:09:55', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1a04395d-fd2a-4a2f-b012-f63394fc7f5b'	System	16 Oct 2020 01:10:29
User entered 'None (0)'	System	16 Oct 2020 01:10:29

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:09:58', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1a04395d-fd2a-4a2f-b012-f63394fc7f5b'	System	16 Oct 2020 01:10:29
User entered 'None (0)'	System	16 Oct 2020 01:10:29

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:10:01', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1a04395d-fd2a-4a2f-b012-f63394fc7f5b'	System	16 Oct 2020 01:10:29
User entered 'None (0)'	System	16 Oct 2020 01:10:29

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:10:07', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1a04395d-fd2a-4a2f-b012-f63394fc7f5b'	System	16 Oct 2020 01:10:29
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	16 Oct 2020 01:10:29

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:10:11', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1a04395d-fd2a-4a2f-b012-f63394fc7f5b'	System	16 Oct 2020 01:10:29
User entered 'None (0)'	System	16 Oct 2020 01:10:29

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:10:14', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1a04395d-fd2a-4a2f-b012-f63394fc7f5b'	System	16 Oct 2020 01:10:29
User entered 'No (N)'	System	16 Oct 2020 01:10:29

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-15T20:10:25', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1a04395d-fd2a-4a2f-b012-f63394fc7f5b'	System	16 Oct 2020 01:10:29
User entered '15 Oct 2020 20:10'	System	16 Oct 2020 01:10:29

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '15 Oct 2020 13:25'	System	15 Oct 2020 14:49:22



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 2'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:13:31', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b168b7f-85ae-40fe-a701-6194ae4f300c'	System	17 Oct 2020 00:14:13
User entered 'None (0)'	System	17 Oct 2020 00:14:13

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:13:35', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b168b7f-85ae-40fe-a701-6194ae4f300c'	System	17 Oct 2020 00:14:13
User entered 'None (0)'	System	17 Oct 2020 00:14:13

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:13:37', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b168b7f-85ae-40fe-a701-6194ae4f300c'	System	17 Oct 2020 00:14:13
User entered 'None (0)'	System	17 Oct 2020 00:14:13

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:13:45', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b168b7f-85ae-40fe-a701-6194ae4f300c'	System	17 Oct 2020 00:14:13
User entered 'None (0)'	System	17 Oct 2020 00:14:13

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:13:48', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b168b7f-85ae-40fe-a701-6194ae4f300c'	System	17 Oct 2020 00:14:13
User entered 'None (0)'	System	17 Oct 2020 00:14:13

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:13:53', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b168b7f-85ae-40fe-a701-6194ae4f300c'	System	17 Oct 2020 00:14:13
User entered 'None (0)'	System	17 Oct 2020 00:14:13



US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:14:05', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b168b7f-85ae-40fe-a701-6194ae4f300c'	System	17 Oct 2020 00:14:13
User entered 'No (N)'	System	17 Oct 2020 00:14:13

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-16T19:14:11', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b168b7f-85ae-40fe-a701-6194ae4f300c'	System	17 Oct 2020 00:14:13
User entered '16 Oct 2020 19:14'	System	17 Oct 2020 00:14:13

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 3'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:06:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ced9f801-952b-45d4-9f81-0d7f9560fb37'	System	18 Oct 2020 01:06:42
User entered 'None (0)'	System	18 Oct 2020 01:06:42

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:06:03', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ced9f801-952b-45d4-9f81-0d7f9560fb37'	System	18 Oct 2020 01:06:42
User entered 'None (0)'	System	18 Oct 2020 01:06:42

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:06:06', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ced9f801-952b-45d4-9f81-0d7f9560fb37'	System	18 Oct 2020 01:06:42
User entered 'None (0)'	System	18 Oct 2020 01:06:42



US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:06:09', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ced9f801-952b-45d4-9f81-0d7f9560fb37'	System	18 Oct 2020 01:06:42
User entered 'None (0)'	System	18 Oct 2020 01:06:42

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:06:12', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ced9f801-952b-45d4-9f81-0d7f9560fb37'	System	18 Oct 2020 01:06:42
User entered 'None (0)'	System	18 Oct 2020 01:06:42

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:06:15', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ced9f801-952b-45d4-9f81-0d7f9560fb37'	System	18 Oct 2020 01:06:42
User entered 'None (0)'	System	18 Oct 2020 01:06:42

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:06:25', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ced9f801-952b-45d4-9f81-0d7f9560fb37'	System	18 Oct 2020 01:06:42
User entered 'No (N)'	System	18 Oct 2020 01:06:42

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-17T20:06:37', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ced9f801-952b-45d4-9f81-0d7f9560fb37'	System	18 Oct 2020 01:06:42
User entered '17 Oct 2020 20:06'	System	18 Oct 2020 01:06:42

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 4'	System	15 Oct 2020 14:49:22



US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:51:56', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '7f2eed4e-70ac-4352-a490-f06765325e10'	System	19 Oct 2020 00:52:25
User entered 'None (0)'	System	19 Oct 2020 00:52:25

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:51:59', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '7f2eed4e-70ac-4352-a490-f06765325e10'	System	19 Oct 2020 00:52:25
User entered 'None (0)'	System	19 Oct 2020 00:52:25

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:52:02', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '7f2eed4e-70ac-4352-a490-f06765325e10'	System	19 Oct 2020 00:52:25
User entered 'None (0)'	System	19 Oct 2020 00:52:25

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:52:04', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '7f2eed4e-70ac-4352-a490-f06765325e10'	System	19 Oct 2020 00:52:25
User entered 'None (0)'	System	19 Oct 2020 00:52:25

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:52:07', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '7f2eed4e-70ac-4352-a490-f06765325e10'	System	19 Oct 2020 00:52:25
User entered 'None (0)'	System	19 Oct 2020 00:52:25

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:52:10', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '7f2eed4e-70ac-4352-a490-f06765325e10'	System	19 Oct 2020 00:52:25
User entered 'None (0)'	System	19 Oct 2020 00:52:25

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:52:17', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '7f2eed4e-70ac-4352-a490-f06765325e10'	System	19 Oct 2020 00:52:25
User entered 'No (N)'	System	19 Oct 2020 00:52:25

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-18T19:52:22', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '7f2eed4e-70ac-4352-a490-f06765325e10'	System	19 Oct 2020 00:52:25
User entered '18 Oct 2020 19:52'	System	19 Oct 2020 00:52:25



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 5'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:52:45', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b5d2c5b-90d0-41ea-8199-1f8fc1b46d8b'	System	19 Oct 2020 23:53:20
User entered 'None (0)'	System	19 Oct 2020 23:53:20

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:52:47', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b5d2c5b-90d0-41ea-8199-1f8fc1b46d8b'	System	19 Oct 2020 23:53:20
User entered 'None (0)'	System	19 Oct 2020 23:53:20

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:52:52', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b5d2c5b-90d0-41ea-8199-1f8fc1b46d8b'	System	19 Oct 2020 23:53:20
User entered 'None (0)'	System	19 Oct 2020 23:53:20

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:52:55', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b5d2c5b-90d0-41ea-8199-1f8fc1b46d8b'	System	19 Oct 2020 23:53:20
User entered 'None (0)'	System	19 Oct 2020 23:53:20

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:52:58', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b5d2c5b-90d0-41ea-8199-1f8fc1b46d8b'	System	19 Oct 2020 23:53:20
User entered 'None (0)'	System	19 Oct 2020 23:53:20



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:53:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b5d2c5b-90d0-41ea-8199-1f8fc1b46d8b'	System	19 Oct 2020 23:53:20
User entered 'None (0)'	System	19 Oct 2020 23:53:20

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:53:11', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b5d2c5b-90d0-41ea-8199-1f8fc1b46d8b'	System	19 Oct 2020 23:53:20
User entered 'No (N)'	System	19 Oct 2020 23:53:20

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-19T18:53:17', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5b5d2c5b-90d0-41ea-8199-1f8fc1b46d8b'	System	19 Oct 2020 23:53:20
User entered '19 Oct 2020 18:53'	System	19 Oct 2020 23:53:20

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 6'	System	15 Oct 2020 14:49:22

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:04:06', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5ca5ae1d-aae5-4778-8e0f-126b21e5ff7f'	System	21 Oct 2020 00:04:39
User entered 'None (0)'	System	21 Oct 2020 00:04:39

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:04:10', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5ca5ae1d-aae5-4778-8e0f-126b21e5ff7f'	System	21 Oct 2020 00:04:39
User entered 'None (0)'	System	21 Oct 2020 00:04:39



US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:04:13', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5ca5ae1d-aae5-4778-8e0f-126b21e5ff7f'	System	21 Oct 2020 00:04:39
User entered 'None (0)'	System	21 Oct 2020 00:04:39

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:04:18', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5ca5ae1d-aae5-4778-8e0f-126b21e5ff7f'	System	21 Oct 2020 00:04:39
User entered 'None (0)'	System	21 Oct 2020 00:04:39

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:04:20', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5ca5ae1d-aae5-4778-8e0f-126b21e5ff7f'	System	21 Oct 2020 00:04:39
User entered 'None (0)'	System	21 Oct 2020 00:04:39

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:04:22', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5ca5ae1d-aae5-4778-8e0f-126b21e5ff7f'	System	21 Oct 2020 00:04:39
User entered 'None (0)'	System	21 Oct 2020 00:04:39

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:04:27', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5ca5ae1d-aae5-4778-8e0f-126b21e5ff7f'	System	21 Oct 2020 00:04:39
User entered 'No (N)'	System	21 Oct 2020 00:04:39

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-20T19:04:35', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5ca5ae1d-aae5-4778-8e0f-126b21e5ff7f' User entered '20 Oct 2020 19:04'	System	21 Oct 2020 00:04:39
	System	21 Oct 2020 00:04:39

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 14:49:22



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	15 Oct 2020 14:49:22
User entered 'Day 7'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:31:23', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd8b5d636-26da-4050-a87b-a7ed9c3ff4c9'	System	22 Oct 2020 00:31:59
User entered 'None (0)'	System	22 Oct 2020 00:31:59

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:31:28', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd8b5d636-26da-4050-a87b-a7ed9c3ff4c9'	System	22 Oct 2020 00:31:59
User entered 'None (0)'	System	22 Oct 2020 00:31:59

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:31:33', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd8b5d636-26da-4050-a87b-a7ed9c3ff4c9'	System	22 Oct 2020 00:31:59
User entered 'None (0)'	System	22 Oct 2020 00:31:59

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:31:38', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd8b5d636-26da-4050-a87b-a7ed9c3ff4c9'	System	22 Oct 2020 00:31:59
User entered 'None (0)'	System	22 Oct 2020 00:31:59

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:31:41', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd8b5d636-26da-4050-a87b-a7ed9c3ff4c9'	System	22 Oct 2020 00:31:59
User entered 'None (0)'	System	22 Oct 2020 00:31:59

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:31:44', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd8b5d636-26da-4050-a87b-a7ed9c3ff4c9'	System	22 Oct 2020 00:31:59
User entered 'None (0)'	System	22 Oct 2020 00:31:59

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:31:50', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd8b5d636-26da-4050-a87b-a7ed9c3ff4c9'	System	22 Oct 2020 00:31:59
User entered 'No (N)'	System	22 Oct 2020 00:31:59



**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-10-21T19:31:56', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd8b5d636-26da-4050-a87b-a7ed9c3ff4c9'	System	22 Oct 2020 00:31:59
User entered '21 Oct 2020 19:31'	System	22 Oct 2020 00:31:59

US3492178

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 14:49:22

**US3492178**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	23 Oct 2020 15:23:36

**US3492178**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '22 Oct 2020'	Gizelle Alvarez (b) (4)	23 Oct 2020 15:23:36

US3492178

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Contact Made (CONTACT MADE)'	Gizelle Alvarez (b) (4)	23 Oct 2020 15:23:36

**US3492178**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	Gizelle Alvarez (b) (4)	23 Oct 2020 15:23:36

US3492178

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	23 Oct 2020 15:23:40



**US3492178**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'I'	System	23 Oct 2020 15:23:40

**US3492178**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:22:24

**US3492178**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:22:24

**US3492178**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:22:24

**US3492178**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:22:24

US3492178

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:22:13

**US3492178**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'I'	System	30 Oct 2020 15:22:13

US3492178

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:30:02



US3492178

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:30:02

US3492178

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:30:02

US3492178

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:30:02

US3492178

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:30:10

**US3492178**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'I'	System	06 Nov 2020 15:30:10

**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:06:41

**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:06:41

US3492178

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:06:41



**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User entered 'VISIT3'	System	12 Nov 2020 14:06:41

US3492178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:07

US3492178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:07

**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '08:17'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:07

**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User entered '12 Nov 2020 08:17'	System	12 Nov 2020 16:00:07

US3492178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:07

US3492178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:07

**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'not specified'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:07



**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '71'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:07

**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User entered 'bpm'	System	12 Nov 2020 16:00:07

US3492178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '18'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:07

US3492178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User entered 'breaths/min'	System	12 Nov 2020 16:00:07

US3492178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '120'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:07

US3492178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User entered 'mmHg'	System	12 Nov 2020 16:00:07

US3492178

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '74'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:07

**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User entered 'mmHg'	System	12 Nov 2020 16:00:07



**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47

**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47

US3492178

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:20

US3492178

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:20

US3492178

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:15

US3492178

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:15

**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '08:25'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:59:15

**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:47
User entered '12 Nov 2020 08:25'	System	12 Nov 2020 15:59:15



**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:00:25

**US3492178**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'I'	System	12 Nov 2020 16:00:25

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered 'Day 64'	System	17 Sep 2020 15:38:11

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-11-18T11:06:48', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'cf7d7e41-83c2-44f8-9910-e51ecdd1d4b5'	System	18 Nov 2020 17:07:10
User entered 'No (N)'	System	18 Nov 2020 17:07:10

US3492178

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:24

Have you been exposed to someone with 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 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-11-18T11:06:57', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'cf7d7e41-83c2-44f8-9910-e51ecdd1d4b5'	System	18 Nov 2020 17:07:10
User entered 'No (N)'	System	18 Nov 2020 17:07:10

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-11-18T11:07:04', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'cf7d7e41-83c2-44f8-9910-e51ecdd1d4b5'	System	18 Nov 2020 17:07:10
User entered '18 Nov 2020 11:07:04'	System	18 Nov 2020 17:07:10

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered '17 Nov 2020 00:01'	System	17 Sep 2020 15:38:11

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:42:42
Data entry locked.	System	17 Sep 2020 15:38:11
User entered '21 Nov 2020 23:59'	System	17 Sep 2020 15:38:11



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2020-11-25T11:21:41', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '84e834c1-0b81-4cbe-84e5-13584371699d'	System	25 Nov 2020 17:21:57
User entered 'No (N)'	System	25 Nov 2020 17:21:57

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2020-11-25T11:21:49', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '84e834c1-0b81-4cbe-84e5-13584371699d'	System	25 Nov 2020 17:21:57
User entered 'No (N)'	System	25 Nov 2020 17:21:57

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-11-25T11:21:54', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '84e834c1-0b81-4cbe-84e5-13584371699d'	System	25 Nov 2020 17:21:57
User entered '25 Nov 2020 11:21:54'	System	25 Nov 2020 17:21:57

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2020-12-01T12:35:12', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '16937678-4108-4663-9791-894748994243'	System	01 Dec 2020 18:35:28
User entered 'No (N)'	System	01 Dec 2020 18:35:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2020-12-01T12:35:19', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '16937678-4108-4663-9791-894748994243'	System	01 Dec 2020 18:35:28
User entered 'No (N)'	System	01 Dec 2020 18:35:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-12-01T12:35:24', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '16937678-4108-4663-9791-894748994243'	System	01 Dec 2020 18:35:28
User entered '01 Dec 2020 12:35:24'	System	01 Dec 2020 18:35:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2020-12-05T10:57:11', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'c2c2b2dc-21bb-4f37-bc4d-ce9713bdfc82'	System	05 Dec 2020 16:57:23
User entered 'No (N)'	System	05 Dec 2020 16:57:23

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2020-12-05T10:57:15', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'c2c2b2dc-21bb-4f37-bc4d-ce9713bdfc82'	System	05 Dec 2020 16:57:23
User entered 'No (N)'	System	05 Dec 2020 16:57:23

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-12-05T10:57:19', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'c2c2b2dc-21bb-4f37-bc4d-ce9713bdfc82'	System	05 Dec 2020 16:57:23
User entered '05 Dec 2020 10:57:19'	System	05 Dec 2020 16:57:23



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2020-12-14T10:37:39', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '36b37f40-8da5-4fbc-a791-359d12b0c742'	System	14 Dec 2020 16:38:00
User entered 'No (N)'	System	14 Dec 2020 16:38:00

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2020-12-14T10:37:45', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '36b37f40-8da5-4fbc-a791-359d12b0c742'	System	14 Dec 2020 16:38:00
User entered 'No (N)'	System	14 Dec 2020 16:38:00

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-12-14T10:37:55', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '36b37f40-8da5-4fbc-a791-359d12b0c742'	System	14 Dec 2020 16:38:00
User entered '14 Dec 2020 10:37:55'	System	14 Dec 2020 16:38:00

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 09:11:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2020-12-22T16:41:29', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'dd4ff50e-5ab0-4e8f-b377-6768ec632fbe'	System	22 Dec 2020 22:41:44
User entered 'No (N)'	System	22 Dec 2020 22:41:44

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2020-12-22T16:41:35', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'dd4ff50e-5ab0-4e8f-b377-6768ec632fbe'	System	22 Dec 2020 22:41:44
User entered 'No (N)'	System	22 Dec 2020 22:41:44

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2020-12-22T16:41:40', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'dd4ff50e-5ab0-4e8f-b377-6768ec632fbe' User entered '22 Dec 2020 16:41:40'	System	22 Dec 2020 22:41:44
	System	22 Dec 2020 22:41:44

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-01-02T12:26:19', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'dfc6e477-9c9a-4b42-89c0-29a5f63c5a81'	System	02 Jan 2021 18:27:23
User entered 'Yes (Y)'	System	02 Jan 2021 18:27:23

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-01-02T12:26:23', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'dfc6e477-9c9a-4b42-89c0-29a5f63c5a81'	System	02 Jan 2021 18:27:23
User entered 'No (N)'	System	02 Jan 2021 18:27:23

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-01-02T12:26:28', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'dfc6e477-9c9a-4b42-89c0-29a5f63c5a81'	System	02 Jan 2021 18:27:23
User entered 'No (N)'	System	02 Jan 2021 18:27:23

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-01-02T12:26:40', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'dfc6e477-9c9a-4b42-89c0-29a5f63c5a81'	System	02 Jan 2021 18:27:23
User entered 'Yes (Y)'	System	02 Jan 2021 18:27:23

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Please 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 (98c67dc2ab926511)', Time: '2021-01-02T12:27:01', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'dfc6e477-9c9a-4b42-89c0-29a5f63c5a81'	System	02 Jan 2021 18:27:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 18:27:23

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-01-02T12:27:12', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'dfc6e477-9c9a-4b42-89c0-29a5f63c5a81'	System	02 Jan 2021 18:27:23
User entered '02 Jan 2021 12:27:12'	System	02 Jan 2021 18:27:23



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-01-13T08:04:21', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '6426d723-0b18-484a-a351-597e1dd42904'	System	13 Jan 2021 14:05:14
User entered 'Yes (Y)'	System	13 Jan 2021 14:05:14

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-01-13T08:04:27', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '6426d723-0b18-484a-a351-597e1dd42904'	System	13 Jan 2021 14:05:14
User entered 'No (N)'	System	13 Jan 2021 14:05:14

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-01-13T08:04:38', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '6426d723-0b18-484a-a351-597e1dd42904'	System	13 Jan 2021 14:05:14
User entered 'No (N)'	System	13 Jan 2021 14:05:14

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-01-13T08:04:45', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '6426d723-0b18-484a-a351-597e1dd42904'	System	13 Jan 2021 14:05:14
User entered 'Yes (Y)'	System	13 Jan 2021 14:05:14

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Please 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 (98c67dc2ab926511)', Time: '2021-01-13T08:04:51', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '6426d723-0b18-484a-a351-597e1dd42904'	System	13 Jan 2021 14:05:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Jan 2021 14:05:14



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-01-13T08:05:01', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '6426d723-0b18-484a-a351-597e1dd42904'	System	13 Jan 2021 14:05:14
User entered '13 Jan 2021 08:05:01'	System	13 Jan 2021 14:05:14

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-01-16T21:03:36', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '82cbc574-b09b-4cfc-8107-a2e06adbd382'	System	17 Jan 2021 03:03:53
User entered 'No (N)'	System	17 Jan 2021 03:03:53

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-01-16T21:03:40', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '82cbc574-b09b-4cfc-8107-a2e06adbd382'	System	17 Jan 2021 03:03:53
User entered 'No (N)'	System	17 Jan 2021 03:03:53

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-01-16T21:03:49', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '82cbc574-b09b-4cfc-8107-a2e06adbd382'	System	17 Jan 2021 03:03:53
User entered '16 Jan 2021 21:03:49'	System	17 Jan 2021 03:03:53

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-01-24T10:42:24', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '7843c5d8-fc5f-43f2-b571-fc762ab52989'	System	24 Jan 2021 16:42:42
User entered 'No (N)'	System	24 Jan 2021 16:42:42

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-01-24T10:42:30', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '7843c5d8-fc5f-43f2-b571-fc762ab52989'	System	24 Jan 2021 16:42:42
User entered 'No (N)'	System	24 Jan 2021 16:42:42

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-01-24T10:42:35', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '7843c5d8-fc5f-43f2-b571-fc762ab52989'	System	24 Jan 2021 16:42:42
User entered '24 Jan 2021 10:42:35'	System	24 Jan 2021 16:42:42

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:11:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-02-01T20:41:24', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '0761c7bf-6554-422d-a981-34fa5f90dbaf'	System	02 Feb 2021 02:41:38
User entered 'No (N)'	System	02 Feb 2021 02:41:38

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-02-01T20:41:29', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '0761c7bf-6554-422d-a981-34fa5f90dbaf'	System	02 Feb 2021 02:41:38
User entered 'No (N)'	System	02 Feb 2021 02:41:38

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-02-01T20:41:34', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '0761c7bf-6554-422d-a981-34fa5f90dbaf'	System	02 Feb 2021 02:41:38
User entered '01 Feb 2021 20:41:34'	System	02 Feb 2021 02:41:38

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-02-08T07:38:12', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1662bc9e-b71c-45e9-8c5d-1892dbc373b0'	System	08 Feb 2021 13:38:26
User entered 'No (N)'	System	08 Feb 2021 13:38:26

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-02-08T07:38:18', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1662bc9e-b71c-45e9-8c5d-1892dbc373b0'	System	08 Feb 2021 13:38:26
User entered 'No (N)'	System	08 Feb 2021 13:38:26



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-02-08T07:38:22', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '1662bc9e-b71c-45e9-8c5d-1892dbc373b0'	System	08 Feb 2021 13:38:26
User entered '08 Feb 2021 07:38:22'	System	08 Feb 2021 13:38:26

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-02-16T19:14:14', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5ffc5267-85bc-454c-8bcc-a5b3e2d8c1b4'	System	17 Feb 2021 01:15:26
User entered 'Yes (Y)'	System	17 Feb 2021 01:15:26

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-02-16T19:14:28', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5ffc5267-85bc-454c-8bcc-a5b3e2d8c1b4'	System	17 Feb 2021 01:15:26
User entered 'No (N)'	System	17 Feb 2021 01:15:26

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-02-16T19:15:03', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5ffc5267-85bc-454c-8bcc-a5b3e2d8c1b4'	System	17 Feb 2021 01:15:26
User entered 'No (N)'	System	17 Feb 2021 01:15:26

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-02-16T19:14:44', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5ffc5267-85bc-454c-8bcc-a5b3e2d8c1b4'	System	17 Feb 2021 01:15:26
User entered 'No (N)'	System	17 Feb 2021 01:15:26



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-02-16T19:15:22', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '5ffc5267-85bc-454c-8bcc-a5b3e2d8c1b4'	System	17 Feb 2021 01:15:26
User entered '16 Feb 2021 19:15:22'	System	17 Feb 2021 01:15:26

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-02-23T09:33:23', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '31d02ac3-3cc8-477a-82a6-90709022fff3'	System	23 Feb 2021 15:33:34
User entered 'No (N)'	System	23 Feb 2021 15:33:34

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-02-23T09:33:26', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '31d02ac3-3cc8-477a-82a6-90709022fff3'	System	23 Feb 2021 15:33:34
User entered 'No (N)'	System	23 Feb 2021 15:33:34

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-02-23T09:33:30', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '31d02ac3-3cc8-477a-82a6-90709022fff3' User entered '23 Feb 2021 09:33:30'	System	23 Feb 2021 15:33:34
	System	23 Feb 2021 15:33:34

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-03-02T09:54:01-06:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '429fcc5a-7f31-4201-9aee-ff2395a0b728'	System	02 Mar 2021 15:54:15
User entered 'No (N)'	System	02 Mar 2021 15:54:15

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-03-02T09:54:05-06:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '429fcc5a-7f31-4201-9aee-ff2395a0b728'	System	02 Mar 2021 15:54:15
User entered 'No (N)'	System	02 Mar 2021 15:54:15

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-03-02T09:54:10-06:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '429fcc5a-7f31-4201-9aee-ff2395a0b728'	System	02 Mar 2021 15:54:15
User entered '02 Mar 2021 09:54:10'	System	02 Mar 2021 15:54:15

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:11:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-03-07T11:20:58-06:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'c4ef2513-0f9a-4295-94ab-3e1c811f9981'	System	07 Mar 2021 17:21:10
User entered 'No (N)'	System	07 Mar 2021 17:21:10

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-03-07T11:21:03-06:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'c4ef2513-0f9a-4295-94ab-3e1c811f9981'	System	07 Mar 2021 17:21:10
User entered 'No (N)'	System	07 Mar 2021 17:21:10

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-03-07T11:21:06-06:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'c4ef2513-0f9a-4295-94ab-3e1c811f9981'	System	07 Mar 2021 17:21:10
User entered '07 Mar 2021 11:21:06'	System	07 Mar 2021 17:21:10

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-03-13T23:07:06-06:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e9cc3f95-1070-4eb2-a80b-efcd7176ba57'	System	14 Mar 2021 05:10:00
User entered 'No (N)'	System	14 Mar 2021 05:10:00

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-03-13T23:07:21-06:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e9cc3f95-1070-4eb2-a80b-efcd7176ba57'	System	14 Mar 2021 05:10:00
User entered 'No (N)'	System	14 Mar 2021 05:10:00



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-03-13T23:07:25-06:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'e9cc3f95-1070-4eb2-a80b-efcd7176ba57'	System	14 Mar 2021 05:10:00
User entered '13 Mar 2021 23:07:25'	System	14 Mar 2021 05:10:00

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-03-21T23:01:01-05:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '058a64c9-5040-4a99-bca1-8f51b9923788'	System	22 Mar 2021 04:02:19
User entered 'No (N)'	System	22 Mar 2021 04:02:19

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-03-21T23:01:05-05:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '058a64c9-5040-4a99-bca1-8f51b9923788'	System	22 Mar 2021 04:02:19
User entered 'No (N)'	System	22 Mar 2021 04:02:19

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-03-21T23:01:09-05:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '058a64c9-5040-4a99-bca1-8f51b9923788'	System	22 Mar 2021 04:02:19
User entered '21 Mar 2021 23:01:09'	System	22 Mar 2021 04:02:19

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-04-07T16:19:04-05:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ccf5cd96-ebb9-42be-8caf-a8cab8ae2f85'	System	07 Apr 2021 21:19:17
User entered 'No (N)'	System	07 Apr 2021 21:19:17

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-04-07T16:19:09-05:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ccf5cd96-ebb9-42be-8caf-a8cab8ae2f85'	System	07 Apr 2021 21:19:17
User entered 'No (N)'	System	07 Apr 2021 21:19:17

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-04-07T16:19:13-05:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'ccf5cd96-ebb9-42be-8caf-a8cab8ae2f85'	System	07 Apr 2021 21:19:17
User entered '07 Apr 2021 16:19:13'	System	07 Apr 2021 21:19:17



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-04-12T12:57:21-05:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '0c2fafd0-9b4d-407b-bd44-5eac327c171'	System	12 Apr 2021 17:57:41
User entered 'No (N)'	System	12 Apr 2021 17:57:41

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-04-12T12:57:32-05:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '0c2fafd0-9b4d-407b-bd44-5eac327c171'	System	12 Apr 2021 17:57:41
User entered 'No (N)'	System	12 Apr 2021 17:57:41

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-04-12T12:57:37-05:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '0c2fafd0-9b4d-407b-bd44-5eac327c171'	System	12 Apr 2021 17:57:41
User entered '12 Apr 2021 12:57:37'	System	12 Apr 2021 17:57:41

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 09:11:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[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 (98c67dc2ab926511)', Time: '2021-04-18T16:27:38-05:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '0a234e81-4c88-4626-bda4-fdc892625d38' User entered 'No (N)'	System	18 Apr 2021 21:27:48
	System	18 Apr 2021 21:27:48

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

Have you been exposed to someone with 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 (98c67dc2ab926511)', Time: '2021-04-18T16:27:42-05:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '0a234e81-4c88-4626-bda4-fdc892625d38'	System	18 Apr 2021 21:27:48
User entered 'No (N)'	System	18 Apr 2021 21:27:48

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-04-18T16:27:46-05:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: '0a234e81-4c88-4626-bda4-fdc892625d38'	System	18 Apr 2021 21:27:48
User entered '18 Apr 2021 16:27:46'	System	18 Apr 2021 21:27:48

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:11:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 09:11:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:11:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 09:11:28



**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 09:11:28



**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 09:11:28

**US3492178**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:11:28
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 09:11:28

US3492178

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:00:24**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:18:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-03-02T09:53:44-06:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd507a213-a014-4490-879b-f064077a27a9'	System	02 Mar 2021 15:53:54
User entered 'No (N)'	System	02 Mar 2021 15:53:54



**US3492178**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:18:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98c67dc2ab926511)', Time: '2021-03-02T09:53:49-06:00', User OID: 'PatientReportedOutcome (US3492178)', ODM File OID: 'd507a213-a014-4490-879b-f064077a27a9'	System	02 Mar 2021 15:53:54
User entered '02 Mar 2021 09:53:49'	System	02 Mar 2021 15:53:54

**US3492178**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	Ian Feather (b) (4)	08 Dec 2020 14:28:55

**US3492178**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '08 Dec 2020'	Ian Feather (b) (4)	08 Dec 2020 14:28:55

**US3492178**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4)	08 Dec 2020 14:28:55

**US3492178**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	Ian Feather (b) (4)	08 Dec 2020 14:28:55

**US3492178**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	Ian Feather (b) (4)	08 Dec 2020 14:29:01

**US3492178**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:34:04
User entered 'I'	System	08 Dec 2020 14:29:01

**US3492178**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	10 Feb 2021 17:14:56



**US3492178**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '13 Jan 2021'	Nia Moragne-O'Neal (b) (4)	10 Feb 2021 17:14:56

**US3492178**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	10 Feb 2021 17:14:56

US3492178

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	Nia Moragne-O'Neal (b) (4)	10 Feb 2021 17:14:56

**US3492178**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	10 Feb 2021 17:14:59

**US3492178**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User entered 'I'	System	10 Feb 2021 17:14:59

**US3492178**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	10 Feb 2021 17:15:10

**US3492178**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '10 Feb 2021'	Nia Moragne-O'Neal (b) (4)	10 Feb 2021 17:15:10

**US3492178**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	10 Feb 2021 17:15:10



**US3492178**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	Nia Moragne-O'Neal (b) (4)	10 Feb 2021 17:15:10

**US3492178**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	10 Feb 2021 17:15:13

**US3492178**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User entered 'I'	System	10 Feb 2021 17:15:13

**US3492178**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	11 Mar 2021 14:27:22

**US3492178**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '11 Mar 2021'	Nia Moragne-O'Neal (b) (4)	11 Mar 2021 14:27:22

**US3492178**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	11 Mar 2021 14:27:22

**US3492178**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered empty.	Nia Moragne-O'Neal (b) (4)	11 Mar 2021 14:27:22

**US3492178**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	11 Mar 2021 14:27:25



**US3492178**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:42:46
User entered 'I'	System	11 Mar 2021 14:27:25

US3492178

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:57:04
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 15:57:04
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 06:13:12
Query 'Data is required. Please complete.' answered with 'visit has not been performed yet' (Site from System).	(b) (4), (b) (6)	22 Mar 2021 13:12:40
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 13:11:35
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:11:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 17:43:21

US3492178

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:57:04
User entered '13 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 15:57:04
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
	(b) (4)	
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	22 Mar 2021 13:11:35
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	22 Mar 2021 13:11:35
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:11:35
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	12 Mar 2021 17:43:21
User entered '12 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 17:43:21

US3492178

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:24

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 15:57:04
User entered 'Clinic (Clinic)' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 15:57:04
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered empty; reason for change Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	22 Mar 2021 13:11:35
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Mar 2021 17:43:21

**US3492178**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	15 Apr 2021 15:57:04
User entered empty.	System	22 Mar 2021 13:11:35
User entered 'VISIT4'	System	12 Mar 2021 17:43:21

**US3492178**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
	(b) (4)	
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	30 Mar 2021 17:40:54
	(b) (4)	

US3492178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 08:53:07
User entered '13 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 15:58:51
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 15:58:11
User entered '13 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 15:57:18
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Apr 2021 15:57:04
User entered '12 Mar 2021'	Marla Schwarber (b) (4) (b) (4)	30 Mar 2021 17:40:54

**US3492178**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
User entered '08:15' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:04
User entered '11:29'	Marla Schwarber (b) (4) (b) (4)	30 Mar 2021 17:40:54



**US3492178**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 08:15'	System	15 Apr 2021 15:58:51
User entered '13 Mar 2021 08:15'	System	15 Apr 2021 15:58:04
User entered '13 Mar 2021 11:29'	System	15 Apr 2021 15:57:18
User entered '12 Mar 2021 11:29'	System	30 Mar 2021 17:40:54

US3492178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
User entered '97.8' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:04
User entered '98.8' F	Marla Schwarber (b) (4) (b) (4)	30 Mar 2021 17:40:54

**US3492178**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
	(b) (4)	
User entered 'Other (Other)'	Marla Schwarber (b) (4)	30 Mar 2021 17:40:54
	(b) (4)	

**US3492178**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
User entered 'tympanic' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:04
User entered 'not specified'	Marla Schwarber (b) (4) (b) (4)	30 Mar 2021 17:40:54

US3492178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
User entered '62' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:04
User entered '63'	Marla Schwarber (b) (4) (b) (4)	30 Mar 2021 17:40:54

**US3492178**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 17:40:54

**US3492178**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
User entered '18' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:04
User entered '20'	Marla Schwarber (b) (4) (b) (4)	30 Mar 2021 17:40:54

**US3492178**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 17:40:54



US3492178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
User entered '125' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:04
User entered '129'	Marla Schwarber (b) (4) (b) (4)	30 Mar 2021 17:40:54

**US3492178**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 17:40:54

US3492178

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
User entered '82' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:04
User entered '74'	Marla Schwarber (b) (4) (b) (4)	30 Mar 2021 17:40:54

**US3492178**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 17:40:54

US3492178

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:24

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:20
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 15:58:20
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 06:13:14
Query 'Data is required. Please complete.' answered with 'visit has not been performed yet' (Site from System).	(b) (4), (b) (6)	22 Mar 2021 13:12:51
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 13:11:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:11:48
User entered 'No (N)'	(b) (4), (b) (6)	17 Mar 2021 16:16:30

US3492178

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:16:30

US3492178

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:44
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 15:58:44
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 06:13:17
Query 'Data is required. Please complete.' answered with 'visit has not been performed yet' (Site from System).	(b) (4), (b) (6)	22 Mar 2021 13:13:02
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 13:12:11
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:12:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 16:16:53

US3492178

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:44
User entered '13 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 15:58:44
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:12:11
User entered '12 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 16:16:53



US3492178

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:29:03
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:44
User entered '08:27' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 15:58:44
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:12:11
User entered '11:29'	(b) (4), (b) (6)	17 Mar 2021 16:16:53

**US3492178**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 08:27'	System	15 Apr 2021 15:58:44
User entered empty.	System	22 Mar 2021 13:12:11
User entered '12 Mar 2021 11:29'	System	17 Mar 2021 16:16:53

US3492178

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'visit has not been performed yet' (Site from System).	(b) (4), (b) (6)	23 Mar 2021 06:13:20
	(b) (4), (b) (6)	22 Mar 2021 13:13:13
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 13:12:20
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:12:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 17:43:27

**US3492178**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 13:12:20
User entered '1'	System	12 Mar 2021 17:43:27

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 16:18:22

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 16:18:22

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 16:18:22

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 16:18:22



**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:24**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:07:34

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:24**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:36:01

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:24**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:07:34

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:24**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:36:01

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:00:24

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:07:34

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:00:24

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:07:34

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:24**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 15:11:15
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 17:07:34

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:24**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 15:11:15
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 17:07:34



**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:24**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:07:34

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:24**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered '1'	System	15 Jan 2021 17:07:34

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered '1'	System	15 Jan 2021 17:07:34

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:00:24**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered empty.	System	20 Jan 2021 14:26:33
DataPoint set to visible.	System	15 Jan 2021 17:07:34

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:00:24**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33



US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered empty.	System	20 Jan 2021 14:26:33
DataPoint set to visible.	System	15 Jan 2021 17:07:34

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	20 Jan 2021 14:26:43
User entered '15 Jan 2021' reason for change: Data Entry Error	System	20 Jan 2021 14:26:43
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Jan 2021 14:26:33
User entered '5 Jan 2021'	System	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '10:55'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered '15 Jan 2021 10:55'	System	20 Jan 2021 14:26:43
User entered '5 Jan 2021 10:55'	System	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '99.1' F	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33



US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'not specified'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '72'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'bpm'	System	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '12'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'breaths/min'	System	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '120'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'mmHg'	System	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '84'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33



**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'mmHg'	System	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:00:24**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered empty.	System	20 Jan 2021 14:26:33
DataPoint set to visible.	System	15 Jan 2021 17:07:34

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '12:36'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33



**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered '15 Jan 2021 12:36'	System	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '99.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 14:59:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 14:59:24
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'not specified' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 14:59:24
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '67'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'bpm'	System	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'breaths/min'	System	20 Jan 2021 14:26:33



**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '114'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'mmHg'	System	20 Jan 2021 14:26:33

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '77'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'mmHg'	System	20 Jan 2021 14:26:33

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:24**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:24:57

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:24**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:24:57

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:59:43

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:59:43



US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:59:43

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'mRNA-1273'	System	20 Jan 2021 14:59:43
DataPoint set to visible.	System	15 Jan 2021 17:07:34

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:59:43

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '12:03'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:59:43

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered '15 Jan 2021 12:03'	System	20 Jan 2021 14:59:43

US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:59:43

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'ONCE'	System	20 Jan 2021 14:59:43

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 14:59:43



**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:12

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:12

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '11:21'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:12

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered '15 Jan 2021 11:21'	System	20 Jan 2021 14:25:12

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:00:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:23:40

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:00:24**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:23:40

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:00:24**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '11:27'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:23:40

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:00:24**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered '15 Jan 2021 11:27'	System	15 Jan 2021 17:23:40



US3492178

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 17:24:08

**US3492178**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered '1'	System	15 Jan 2021 17:24:08

**US3492178**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	Ian Feather (b) (4)	22 Jan 2021 18:14:05

**US3492178**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '22 Jan 2021'	Ian Feather (b) (4)	22 Jan 2021 18:14:05

**US3492178**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4)	22 Jan 2021 18:14:05

**US3492178**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	Ian Feather (b) (4)	22 Jan 2021 18:14:05

**US3492178**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	Ian Feather (b) (4)	22 Jan 2021 18:14:10

**US3492178**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'I'	System	22 Jan 2021 18:14:10



**US3492178**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered '1'	System	22 Jan 2021 18:14:10
DataPoint set to visible.	System	22 Jan 2021 18:14:10

**US3492178**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:37:05

**US3492178**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:37:05

**US3492178**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:37:05

**US3492178**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'OLD29'	System	17 Feb 2021 15:37:05

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:38:53



**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '10:03'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered '12 Feb 2021 10:03'	System	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '71'	(b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'bpm'	System	17 Feb 2021 15:38:53

US3492178

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	17 Feb 2021 15:39:54
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).		17 Feb 2021 15:39:54
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 15:39:54
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		17 Feb 2021 15:38:53
User entered '117'	(b) (4), (b) (6)	17 Feb 2021 15:38:53



**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'breaths/min'	System	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '117' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 15:39:54
User entered '80'	(b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'mmHg'	System	17 Feb 2021 15:38:53

US3492178

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	17 Feb 2021 15:39:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Feb 2021 15:39:54
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 15:39:54
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Feb 2021 15:38:53
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'mmHg'	System	17 Feb 2021 15:39:54
User entered empty.	System	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:38:53



**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '11:07'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered '12 Feb 2021 11:07'	System	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '98.3' F	(b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '65'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'bpm'	System	17 Feb 2021 15:38:53

US3492178

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	17 Feb 2021 15:39:54
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).		17 Feb 2021 15:39:54
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 15:39:54
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		17 Feb 2021 15:38:53
User entered '131'	(b) (4), (b) (6)	17 Feb 2021 15:38:53



**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'breaths/min'	System	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '131' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 15:39:54
User entered '83'	(b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'mmHg'	System	17 Feb 2021 15:38:53

US3492178

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Feb 2021 15:39:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	17 Feb 2021 15:39:54
User entered '83' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 15:39:54
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Feb 2021 15:38:53
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'mmHg'	System	17 Feb 2021 15:39:54
User entered empty.	System	17 Feb 2021 15:38:53

**US3492178**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:24**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:40:03

**US3492178**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:24**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:40:03

**US3492178**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:40:37



**US3492178**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:40:37

US3492178

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:40:37

**US3492178**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'mRNA-1273'	System	17 Feb 2021 15:40:37
DataPoint set to visible.	System	22 Jan 2021 18:14:10

US3492178

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:40:37

**US3492178**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '10:30'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:40:37

**US3492178**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered '12 Feb 2021 10:30'	System	17 Feb 2021 15:40:37

US3492178

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:40:37

**US3492178**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'ONCE'	System	17 Feb 2021 15:40:37



**US3492178**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:24**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 15:40:37

**US3492178**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:41:49

**US3492178**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'I'	System	17 Feb 2021 15:41:49

**US3492178**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	19 Feb 2021 18:10:09

**US3492178**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '19 Feb 2021'	Nia Moragne-O'Neal (b) (4)	19 Feb 2021 18:10:09

**US3492178**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	19 Feb 2021 18:10:09

**US3492178**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered empty.	Nia Moragne-O'Neal (b) (4)	19 Feb 2021 18:10:09

**US3492178**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	19 Feb 2021 18:10:12



**US3492178**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'I'	System	19 Feb 2021 18:10:12

**US3492178**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:43:01

**US3492178**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:43:01

**US3492178**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:43:01

**US3492178**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'OLD57'	System	12 Mar 2021 17:43:01

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:27

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:27

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '11:29'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:27



**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered '12 Mar 2021 11:29'	System	17 Mar 2021 16:17:27

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:27

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:27

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'not specified'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:27

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '63'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:27

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'bpm'	System	17 Mar 2021 16:17:27

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '20'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:27

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'breaths/min'	System	17 Mar 2021 16:17:27



**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '129'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:27

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'mmHg'	System	17 Mar 2021 16:17:27

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '74'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:27

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered 'mmHg'	System	17 Mar 2021 16:17:27

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10

**US3492178**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:24**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10

**US3492178**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:24**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:34

**US3492178**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:24**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:34



**US3492178**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:48

**US3492178**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:48

**US3492178**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '11:29'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:17:48

**US3492178**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:12:10
User entered '12 Mar 2021 11:29'	System	17 Mar 2021 16:17:48

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 08:00:24**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:38:43
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 17:31:41

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09

US3492178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Extremity deformities, PT: Foot deformity, LLT: Bunion - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 21:12:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 21:12:50
Data point term sent to Coder	System	16 Nov 2020 19:40:54
User entered 'pain from bunion to right foot'	(b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25



**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Nov 2020 19:47:07
User entered '12:00' reason for change: Data Entry Error	System	16 Nov 2020 19:47:07
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 19:40:25
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
User entered '17 Sep 2020 12:00'	System	16 Nov 2020 19:47:07
User entered empty.	System	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Nov 2020 19:47:07
User entered '22:00' reason for change: Data Entry Error	System	16 Nov 2020 19:47:07
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 19:40:25
User entered empty.	System	16 Nov 2020 19:40:25



**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
User entered '18 Sep 2020 22:00'	System	16 Nov 2020 19:47:07
User entered empty.	System	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

US3492178

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25



**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25



**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'l'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[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 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
User entered '0'	System	16 Nov 2020 19:40:25

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09
User entered '0'	System	16 Nov 2020 19:40:25



**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:09

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:03:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered	(b) (4)	11 Jan 2021 16:52:45
'USA-US101-2021-mRNA-1273-P301000003'	System	11 Jan 2021 16:52:45
User entered 'New'	(b) (4), (b) (6)	11 Jan 2021 16:52:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis perforated, LLT: Appendicitis perforated - version MedDRA\23.0.	Coder Import (b) (4)	20 Mar 2021 21:29:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Mar 2021 21:29:39
User closed query 'PV Query: Consider revising event term to appendicitis/perforated appendix.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 15:03:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 22:47:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 22:47:51
Data point term sent to Coder	System	17 Mar 2021 16:20:00
Query 'PV Query: Consider revising event term to appendicitis/perforated appendix.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 16:19:45
Coding entries removed.	(b) (4), (b) (6)	17 Mar 2021 16:19:39
User entered 'APPENDICITIS/PERFORATED APPENDIX, S/P APPENDECTOMY' reason for change: Per Query Resolution	(b) (4), (b) (6)	17 Mar 2021 16:19:39
User opened query 'PV Query: Consider revising event term to appendicitis/perforated appendix.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 14:04:36
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis perforated, LLT: Appendicitis perforated - version MedDRA\23.0.	Coder Import (b) (4)	28 Feb 2021 11:50:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Feb 2021 11:50:23
Data point term sent to Coder	System	23 Feb 2021 19:53:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Diana Bahena (b) (4)	23 Feb 2021 19:52:44
	(b) (4)	
Signature has been broken.	Diana Bahena (b) (4)	23 Feb 2021 19:52:44
	(b) (4)	
User entered 'APPENDICITIS (perforated appendix), s/p appendectomy' reason for change: New Information	Diana Bahena (b) (4)	23 Feb 2021 19:52:44
	(b) (4)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	15 Jan 2021 17:00:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Jan 2021 17:00:54
	(b) (4)	
Data point term sent to Coder	System	15 Jan 2021 16:59:46
Coding entries removed.	Andrea Wendrow (b) (4)	15 Jan 2021 16:59:31
	(b) (4)	
User entered 'APPENDICITIS' reason for change: New Information	Andrea Wendrow (b) (4)	15 Jan 2021 16:59:31
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Jan 2021 12:01:08
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Jan 2021 12:01:08
	(b) (4)	
Data point term sent to Coder	System	09 Jan 2021 00:06:29
User entered 'assumed appendicitis'	Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'No (N)'	Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User closed query 'PV Query: Please provide the onset date for the event with signs and symptoms.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:22:09
Query 'PV Query: Please provide the onset date for the event with signs and symptoms.' answered with '-----started with Right lower quadrant pain on 04Jan2020-----' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 18:37:59
User entered '4 Jan 2021' reason for change: Per Query Resolution	(b) (4), (b) (6)	20 Jan 2021 18:37:03
User opened query 'PV Query: Please provide the onset date for the event with signs and symptoms.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 17:30:36
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 16:27:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 16:27:08
User entered '7 Jan 2021' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Jan 2021 16:27:08
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Jan 2021 00:05:38
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	09 Jan 2021 00:05:38



**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Jan 2021 00:05:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 16:27:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 16:27:08
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Jan 2021 16:27:08
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Jan 2021 00:05:38
User entered empty.	Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 11:46:10
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'Outcome Resolved.' (Site from System).	(b) (4), (b) (6)	15 Jan 2021 16:29:24
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Jan 2021 16:27:08
User entered '11 Jan 2021' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Jan 2021 16:27:08
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	09 Jan 2021 00:05:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 22:26:43
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 17:29:27
User entered empty.	System	09 Jan 2021 00:05:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38



**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User closed query 'PV Query: Please provide details regarding hospitalization including admission date, discharge date, and confirm whether or not the subject went to the ICU.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:22:31
Query 'PV Query: Please provide details regarding hospitalization including admission date, discharge date, and confirm whether or not the subject went to the ICU.' answered with '-----admission date, discharge date, ICU info entered-----' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 18:39:18
User opened query 'PV Query: Please provide details regarding hospitalization including admission date, discharge date, and confirm whether or not the subject went to the ICU.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 17:31:05
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		15 Jan 2021 16:27:08
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		15 Jan 2021 16:27:08
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Jan 2021 00:05:38
User entered 'I'	Andrea Wendrow (b) (4) (b) (4)	09 Jan 2021 00:05:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '7 Jan 2021' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	15 Jan 2021 16:27:08
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	09 Jan 2021 00:05:38

US3492178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '11 Jan 2021' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	15 Jan 2021 16:27:08
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	09 Jan 2021 00:05:38

US3492178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User closed query 'Per CDM: Query response indicates "NO". However Admitted to ICU is still recorded as 'Unknown'. Please update as appropriate else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:51:02
Query 'Per CDM: Query response indicates "NO". However Admitted to ICU is still recorded as 'Unknown'. Please update as appropriate else clarify. ' answered with '-----Provided. Thank You-----' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 18:39:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 18:37:03
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), (b) (6)	18 Jan 2021 11:47:55
User opened query 'Per CDM: Query response indicates "NO". However Admitted to ICU is still recorded as 'Unknown'. Please update as appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:47:49
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.' answered with 'No' (Site from System).	(b) (4), (b) (6)	15 Jan 2021 16:27:20
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	09 Jan 2021 00:05:38
User entered 'Unknown (UNK)'	Andrea Wendrow (b) (4) (b) (4)	09 Jan 2021 00:05:38

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Folder: Adverse Events

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Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	20 Jan 2021 18:40:01
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	20 Jan 2021 18:40:01
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	20 Jan 2021 18:40:01
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	20 Jan 2021 18:37:03
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Jan 2021 16:27:08
User entered empty.	Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38



**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '0'	Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '0'	Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'Not Related (NOT RELATED)'	(b) (4) Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

US3492178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'Not Related (NOT RELATED)'	(b) (4) Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

US3492178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	20 Jan 2021 18:40:31
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	20 Jan 2021 18:40:31
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	15 Jan 2021 17:00:24
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Jan 2021 16:30:09
User entered '1' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Jan 2021 16:30:09
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Jan 2021 00:05:38
User entered '0'	Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

US3492178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #12 and 13 indication were STATUS POST PERFORATED APPENDIX and POST SURGICAL PAIN APPENDECTOMY. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 16:28:08
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #12 and 13 indication were STATUS POST PERFORATED APPENDIX and POST SURGICAL PAIN APPENDECTOMY. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 19:53:25
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #12 and 13 indication were STATUS POST PERFORATED APPENDIX and POST SURGICAL PAIN APPENDECTOMY. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 03:41:54
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:57:19
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 18:53:52
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	09 Jan 2021 00:05:38

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered '1' reason for change: New Information	(b) (4)	
	Andrea Wendrow (b) (4)	15 Jan 2021 17:00:24
User entered '0'	(b) (4)	
	Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:50:29
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	20 Jan 2021 18:49:17
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	20 Jan 2021 18:49:17
Comment added 'corrected, query bubble will not go away'.	Andrea Wendrow (b) (4)	15 Jan 2021 17:00:52
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	15 Jan 2021 16:30:09
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	15 Jan 2021 16:30:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Jan 2021 16:30:09
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	15 Jan 2021 16:27:08
User entered 'Unknown (UNKNOWN)'	Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:22:43
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with '-----Recovered/Resolved-----' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 18:51:02
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	20 Jan 2021 18:50:29
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 17:30:01
User entered 'Surgery was successful and per patient, she feels great.' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Jan 2021 16:27:08
User entered empty.	Andrea Wendrow (b) (4)	09 Jan 2021 00:05:38

US3492178

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:19
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)	21 Jan 2021 16:22:57
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:22:50
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 '-----Provided-----' -' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 18:56:38
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 '-----Provided-----' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 18:56:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT SEEN IN EMERGENCY ROOM FOR RIGHT LOWER QUADRANT PAIN ON 07JAN2021. CT SCAN of the abdomen on 7JAN2021 showed perforation of appendix. Participant WAS ADMITTED INTO HOSPITAL FOR APPENDICITIS. LAPAROSCOPIC APPENDECTOMY PERFORMED ON 07JAN2021. PARTICIPANT WAS DISCHARGED WITH AMOXICILLIN / CLAVULANATE POTASSIUM 875/125 1 TAB PO BID X 10 DAYS, HYDROCODONE 5/325 1 TAB PO Q 4H PRN' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 18:55:54
User entered 'PARTICIPANT SEEN IN EMERGENCY ROOM FOR RIGHT LOWER QUADRANT PAIN ON 07JAN2021. CT SCAN WAS PERFORMED ON 07JAN2021 AND WAS ADMITTED INTO HOSPITAL FOR APPENDICITIS. LAPAROSCOPIC APPENDECTOMY PERFORMED ON 07JAN2021. participant was discharged with Amoxicillin / Clavulanate Potassium 875/125 1 tab PO BID x 10 days, Hydrocodone 5/325 1 tab PO Q 4H PRN' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 18:53:52
User entered 'Participant seen in Emergency room for Right Lower Quadrant pain on 07Jan2021. CT scan was performed on 07Jan2021 and was admitted into hospital for appendicitis. Laparoscopic Appendectomy performed on 07Jan2021.' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 18:48:57
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)	15 Jan 2021 17:30:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:24

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 17:29:03
User entered 'Call center received message this afternoon from subject reporting she had been hospitalized and had an appendectomy. No dates or other information left in message. All attempts today to contact subject unsuccessful.'	Andrea Wendrow (b) (4)	(b) (4) 09 Jan 2021 00:05:38

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Jan 2021 00:05:38

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Jan 2021 00:05:38

**US3492178**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Jan 2021 00:05:38



US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:00:24

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:06

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 17:16:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 17:16:53
Data point term sent to Coder	System	17 Sep 2020 17:16:03
User entered 'ALLEGRA'	(b) (4), (b) (6)	17 Sep 2020 17:15:52

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:52

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'SEASONAL ALLERGIES'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:52

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0.5'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:52

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:52

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:52



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'ONCE DAILY, AS NEEDED'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:52

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:52

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:52

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:52

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:52

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:52

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:52

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:15:52



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 17:15:52

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 17:15:52

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 17:15:52

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS, PRODUCT: MONASCUS PURPUREUS, PRODUCTSYNONYM: RED RICE YEAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 17:19:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 17:19:43
Data point term sent to Coder	System	17 Sep 2020 17:19:10
User entered 'RED YEAST RICE'	(b) (4), (b) (6)	17 Sep 2020 17:18:37

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:18:37

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'HYPERLIPIDEMIA'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:18:37

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 07:07:26
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 16:57:18
User entered '1200' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 16:57:05
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 07:20:04
User entered '1'	(b) (4), (b) (6)	17 Sep 2020 17:18:37

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 16:57:05
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	17 Sep 2020 17:18:37



US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:18:37

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:18:37

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:18:37

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:18:37

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:18:37

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:18:37

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:18:37

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)' reason for change: Data Entry Error	Elena Llinas (b) (4)	01 Oct 2020 20:20:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:18:37



US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '24 Sep 2020' reason for change: Data Entry Error	Elena Llinas (b) (4)	01 Oct 2020 20:20:56
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:18:37

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:18:37

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User entered '1'	System	17 Sep 2020 17:18:37

US3492178

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User entered '1'	System	17 Sep 2020 17:18:37

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:26:59
User entered '804 (804)'	System	17 Sep 2020 17:18:37

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Sep 2020 17:19:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:19:43
Data point term sent to Coder	System	17 Sep 2020 17:19:10
User entered 'GABAPENTIN'	(b) (4), (b) (6)	17 Sep 2020 17:19:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'RESTLESS LEG SYNDROME'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:08



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '200'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:08

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:08

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:08

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:08

US3492178

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:08



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:08

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:19:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:19:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 17:19:08

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 17:20:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 17:20:38
Data point term sent to Coder	System	17 Sep 2020 17:20:11
User entered 'MULTIVITAMIN'	(b) (4), (b) (6)	17 Sep 2020 17:19:33



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:33

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'HEALTH MAINTENANCE'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:33

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:33

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:33

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:33

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:33

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:33

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:33



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:24**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:33

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:33

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:33

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)' reason for change: New Information	(b) (4) Nia Moragne-O'Neal	10 Feb 2021 17:15:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:19:33

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Jan 2021' reason for change: New Information	(b) (4)	10 Feb 2021 17:15:38
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:19:33

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:19:33

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User entered '1'	System	17 Sep 2020 17:19:33

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User entered '1'	System	17 Sep 2020 17:19:33



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:06
User entered '804 (804)'	System	17 Sep 2020 17:19:33

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Sep 2020 17:20:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:20:38
Data point term sent to Coder	System	17 Sep 2020 17:20:11
User entered 'VITAMIN D3'	(b) (4), (b) (6)	17 Sep 2020 17:20:03

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:20:03

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'VITAMIN D3 DEFICIENCY'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:20:03

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '1000'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:20:03

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:20:03

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:20:03

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:20:03



US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:20:03

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:20:03

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:20:03

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:20:03

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:20:03

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:20:03

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:20:03

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:20:03



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:20:03

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:20:03

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 17:20:03

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Sep 2020 17:21:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:21:39
Data point term sent to Coder	System	17 Sep 2020 17:21:18
User entered 'MAGNESIUM'	(b) (4), (b) (6)	17 Sep 2020 17:21:11

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:11

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'RESTLESS LEG SYNDROME'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:11

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '400'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:11

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:11



US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:11

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:11

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:11

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:11

US3492178

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:11

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:11

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:11

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:11



US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:11

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:11

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:21:11

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:21:11

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 17:21:11

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STERIODS, PRODUCT: COLLAGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 17:23:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 17:23:44
Data point term sent to Coder	System	17 Sep 2020 17:22:18
User entered 'COLLAGEN'	(b) (4), (b) (6)	17 Sep 2020 17:21:34

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:34

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'HEALTH MAINTENANCE'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:34



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '1'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:34

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:34

US3492178

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:34

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:34

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:34

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:34

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:34

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:34



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:34

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:34

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:34

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:21:34

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:21:34

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:21:34

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 17:21:34

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 16:40:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 16:40:58
Data point term sent to Coder	System	15 Jan 2021 16:40:12
Coding entries removed.	(b) (4), (b) (6)	15 Jan 2021 16:39:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 16:02:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 16:02:32
Data point term sent to Coder	System	12 Nov 2020 16:01:42
Coding entries removed.	(b) (4), (b) (6)	12 Nov 2020 16:01:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 17:23:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 17:23:44
Data point term sent to Coder	System	17 Sep 2020 17:22:19
User entered 'TYLENOL'	(b) (4), (b) (6)	17 Sep 2020 17:22:08



US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:08

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:24

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no Med History that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:32:19
Query 'Per DM CLR: Please note there is no Med History that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' answered with 'see con med line 8, osteoarthritis of the foot' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 13:35:23
User opened query 'Per DM CLR: Please note there is no Med History that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 13:27:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:52:19
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated medical history' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 18:07:42
User entered 'osteoarthritis of the foot' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 16:39:41
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 23:32:08
User closed query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:37:49

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EAB) (1725)

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US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:24

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' answered with 'nothing to put in the medical history, it is just for general pain occasionally' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:02:00
User entered 'general JOINT PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 16:01:31
User opened query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:22:45
User entered 'JOINT PAIN'	(b) (4), (b) (6)	17 Sep 2020 17:22:08

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 07:51:58
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 18:07:47
User entered '650' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 18:07:30
User entered '500' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 16:39:13
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 23:31:57
User entered '750'	(b) (4), (b) (6)	17 Sep 2020 17:22:08

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:08

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:24**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:08

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:08



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:08

US3492178

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:08

US3492178

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 17:22:08



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 17:22:08

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 17:22:08

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
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: NAPROXEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Sep 2020 22:22:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 22:22:45
Data point term sent to Coder	System	17 Sep 2020 17:23:20
User entered 'NAPROXEN'	(b) (4), (b) (6)	17 Sep 2020 17:22:50

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:50

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:24**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'RIGHT FOOT BUNION'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:50

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '500'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:50

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:50

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:50



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:24**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:50

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:24**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:50

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:50

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:50

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'UN UNK 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:50

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 07:54:58
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'this is an ongoing medication along with the foot bunion (see medical history) It is taken whenever the foot bunion gets bad and causes pain to the patient (see adverse event) the adverse event has been resolved but the medication is still ongoing because it is taken as needed when something like the adverse event occurs' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 17:37:32
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 05:24:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:22:50

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:50



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:22:50

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 17:22:50

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 17:22:50

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 17:22:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Dec 2020 16:37:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 16:37:04
Data point term sent to Coder	System	11 Dec 2020 16:55:32
Coding entries removed.	(b) (4), (b) (6)	11 Dec 2020 16:54:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:12:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:12:36
Data point term sent to Coder	System	09 Oct 2020 16:14:28
User entered 'melatonin'	(b) (4), (b) (6)	09 Oct 2020 16:13:58

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
Signature has been broken.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:51:21
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Mar 2021 14:51:21
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:13:58

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:24

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Site response noted, however RESTLESSNESS is an Adverse event please refer to MODERNA PROTOCOL 8.3.1. Adverse Event. Events Meeting the Adverse Event Definition Bullet #2 • New conditions detected or diagnosed after the first dose of IP even though they may have been present before the start of the study.' Update as necessary, else explain.' (Site from DM). Query 'Per DM CLR: Site response noted, however RESTLESSNESS is an Adverse event please refer to MODERNA PROTOCOL 8.3.1. Adverse Event. Events Meeting the Adverse Event Definition Bullet #2 • New conditions detected or diagnosed after the first dose of IP even though they may have been present before the start of the study.' Update as necessary, else explain.' answered with 'the participant has not detected or diagnosed condition for general restlessness, prophylaxis has been changed to yes' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 09:10:45
User opened query 'Per DM CLR: Site response noted, however RESTLESSNESS is an Adverse event please refer to MODERNA PROTOCOL 8.3.1. Adverse Event. Events Meeting the Adverse Event Definition Bullet #2 • New conditions detected or diagnosed after the first dose of IP even though they may have been present before the start of the study.' Update as necessary, else explain.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	23 Feb 2021 06:06:57
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'no underlying condition, just general' (Site from DM).	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'general RESTLESSNESS' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 07:23:50
	(b) (4), (b) (6)	11 Dec 2020 16:55:04
	(b) (4), (b) (6)	11 Dec 2020 16:54:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:24

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 04:31:28
User entered 'restlessness'	(b) (4), (b) (6)	09 Oct 2020 16:13:58



US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '5'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:13:58

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:13:58

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:13:58

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:13:58

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:13:58

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:13:58

US3492178

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:00:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:13:58

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:13:58



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:13:58

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:00:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:13:58

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:13:58

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 16:13:58

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:00:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 16:13:58

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 16:13:58

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 16:13:58

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:24

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS OF THE FOOT should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 06:20:18
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS OF THE FOOT should be recorded, and update con med indication or provide clarification. ' answered with 'participant confirmed that osteoarthritis of the foot did not worsen but she just got around to trying this method' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 16:29:06
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS OF THE FOOT should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 02:12:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIDIOL, PRODUCTSYNONYM: CBD OIL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Feb 2021 07:58:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 07:58:44
Data point term sent to Coder	System	01 Feb 2021 15:20:07
Coding entries removed.	(b) (4), (b) (6)	01 Feb 2021 15:19:10



US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:24

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIDIOL, PRODUCTSYNONYM: CBD OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:53:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:53:06
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	15 Jan 2021 16:51:22 15 Jan 2021 16:50:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIDIOL, PRODUCTSYNONYM: CBD OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 05:15:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 05:15:51
Data point term sent to Coder User entered 'cbd oil'	System (b) (4), (b) (6)	12 Nov 2020 16:03:48 12 Nov 2020 16:02:49

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:49

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:24

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:32:40
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	(b) (4), (b) (6)	15 Feb 2021 13:35:47
answered with 'see con med line 8, osteoarthritis of the foot' (Site from DM).		
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 13:26:48
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User closed query 'Per CDM re-query: Thank you for adding this condition in MH. However please update the indication term to 'OSTEOARTHRITIS OF THE FOOT' to match the MH term to reconcile the data. '	(b) (4), (b) (6)	02 Feb 2021 05:11:01
(Site from DM).		
Query 'Per CDM re-query: Thank you for adding this condition in MH. However please update the indication term to 'OSTEOARTHRITIS OF THE FOOT' to match the MH term to reconcile the data. '	(b) (4), (b) (6)	01 Feb 2021 15:19:16
answered with 'updated' (Site from DM).		
User entered 'OSTEOARTHRITIS of the foot' reason for change: Per Query Resolution	(b) (4), (b) (6)	01 Feb 2021 15:19:10
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	(b) (4), (b) (6)	01 Feb 2021 08:05:27
' (Site from DM).		
User opened query 'Per CDM re-query: Thank you for adding this condition in MH. However please update the indication term to 'OSTEOARTHRITIS OF THE FOOT' to match the MH term to reconcile the data. '	(b) (4), (b) (6)	01 Feb 2021 08:05:24
(Site from DM).		

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:24

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'updated medical history' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 18:08:00
User entered 'Osteoarthritis' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Jan 2021 16:50:40
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 23:34:02
User entered 'general aches and pains'	(b) (4), (b) (6)	12 Nov 2020 16:02:49

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:49

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:49

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'drop'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:49

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:24**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:49



US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:49

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:49

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:49

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'un Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:49

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:49

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:49

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:49

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:02:49



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:02:49

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 16:02:49

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 16:02:49

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Apr 2021 13:46:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Apr 2021 13:46:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 04:40:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 04:40:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:06:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:06:57
Data point term sent to Coder	System	17 Mar 2021 16:31:13
Coding entries removed.	(b) (4), (b) (6)	17 Mar 2021 16:30:41

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:24

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 12:14:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 12:14:55
Data point term sent to Coder	System	23 Feb 2021 19:53:15
Coding entries removed.	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 19:52:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:57:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 14:43:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 14:43:01
Data point term sent to Coder	System	12 Jan 2021 22:40:16
User entered 'Amoxicillin / Clavulnate Potassium 875/125'	(b) (4), (b) (6) (b) (4)	12 Jan 2021 22:39:36

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:00:24**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:39:36

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User closed query 'Per DM CLR: Please note that there is no ongoing AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 06:21:55
Query 'Per DM CLR: Please note that there is no ongoing AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify ' answered with 'updated to say "post" because medication was taken for the appendicitis and the appendectomy but began following the hospital discharge date. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 16:31:23
User entered 'Post APPENDICITIS (PERFORATED APPENDIX), S/P APPENDECTOMY' reason for change: Per Query Resolution	(b) (4), (b) (6)	17 Mar 2021 16:30:41
User opened query 'Per DM CLR: Please note that there is no ongoing AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:39:32
Signature has been broken.	Diana Bahena (b) (4)	23 Feb 2021 19:52:57
User entered 'APPENDICITIS (perforated appendix), s/p appendectomy' reason for change: Data Entry Error	(b) (4) Diana Bahena (b) (4)	23 Feb 2021 19:52:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Status Post Perforated Appendix'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:39:36

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:39:36



US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:39:36

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:39:36

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:39:36

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:00:24**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:39:36

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
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	12 Jan 2021 22:39:53
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 22:39:53
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 22:39:36
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 22:39:36

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:39:36

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:39:36

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:39:36



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:00:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)' reason for change: New Information	Ian Feather (b) (4)	22 Jan 2021 18:12:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Jan 2021 22:39:36

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '21 Jan 2021' reason for change: New Information	Ian Feather (b) (4)	22 Jan 2021 18:12:08
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 22:39:36

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:39:36

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:00:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User entered '2'	System	12 Jan 2021 22:39:36

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User entered '1'	System	12 Jan 2021 22:39:36

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:42
User entered '804 (804)'	System	12 Jan 2021 22:39:36

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Jan 2021 14:31:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 14:31:00
Data point term sent to Coder	System	12 Jan 2021 22:42:20
User entered 'Hydrocodone 5/325'	(b) (4), (b) (6)	12 Jan 2021 22:41:22

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:24**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:41:22



US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:22:13
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' answered with 'see AE line 2, appendicitis, and procedures log line 1, appendectomy' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 13:36:50
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 13:31:31
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Post Surgical Pain Appendectomy'	(b) (4), (b) (6)	12 Jan 2021 22:41:22

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:41:22

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:41:22

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:41:22

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:24**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:41:22

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:24**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'every 4 hours PRN'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:41:22

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:41:22

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:24**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:41:22



**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:41:22

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:41:22

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)' reason for change: New Information	Ian Feather (b) (4)	22 Jan 2021 18:12:50
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 22:41:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Jan 2021 22:41:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 22:41:31
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 22:41:22
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 22:41:22

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '21 Jan 2021' reason for change: New Information	Ian Feather (b) (4)	22 Jan 2021 18:12:50
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 22:41:22

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:41:22

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User entered empty.	System	12 Jan 2021 22:41:22

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User entered empty.	System	12 Jan 2021 22:41:22

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:39
User entered empty.	System	12 Jan 2021 22:41:22



US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 08:23:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 08:23:53
Data point term sent to Coder	System	18 Mar 2021 14:10:47
Data point term sent to Coder	System	17 Mar 2021 16:24:05
Coding entries removed.	(b) (4), (b) (6)	17 Mar 2021 16:23:50
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:57:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:15:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:15:02
Data point term sent to Coder	System	22 Jan 2021 18:14:20
User entered 'ibuprofen'	Ian Feather (b) (4) (b) (4)	22 Jan 2021 18:13:44

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:24**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	Ian Feather (b) (4)	22 Jan 2021 18:13:44

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'PAIN IN SIDE post APPENDECTOMY' reason for change: New Information	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:10:42
User closed query 'Per CDM re-query: Response indicates "pain in her side from her appendectomy"; However the indication is still recorded as "SOLICITED ADVERSE REACTION". Please update the indication as appropriate per response else clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 06:20:45
Query 'Per CDM re-query: Response indicates "pain in her side from her appendectomy"; However the indication is still recorded as "SOLICITED ADVERSE REACTION". Please update the indication as appropriate per response else clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 16:24:39
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:23:50
User entered 'pain in side due to appendectomy' reason for change: Per Query Resolution	(b) (4), (b) (6)	17 Mar 2021 16:23:50
User closed query 'Per DM CLR: Please review and specify the type of Solicited Adverse Reaction (e.g., Headache, Fever, Injection Site Pain, etc). Update and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 06:23:44
User opened query 'Per CDM re-query: Response indicates "pain in her side from her appendectomy"; However the indication is still recorded as "SOLICITED ADVERSE REACTION". Please update the indication as appropriate per response else clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 06:23:42
Query 'Per DM CLR: Please review and specify the type of Solicited Adverse Reaction (e.g., Headache, Fever, Injection Site Pain, etc). Update and reconcile as appropriate.' answered with 'pain in her side from her appendectomy' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 17:16:41
User opened query 'Per DM CLR: Please review and specify the type of Solicited Adverse Reaction (e.g., Headache, Fever, Injection Site Pain, etc). Update and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 00:19:41

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EAB) (1725)

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**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:24**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
	(b) (4)	
User entered 'solicited adverse reaction'	Ian Feather (b) (4)	22 Jan 2021 18:13:44
	(b) (4)	

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:24**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '200'	Ian Feather (b) (4)	22 Jan 2021 18:13:44

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'mg (mg)'	Ian Feather (b) (4)	22 Jan 2021 18:13:44

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	Ian Feather (b) (4)	22 Jan 2021 18:13:44

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'once (ONCE)'	Ian Feather (b) (4)	22 Jan 2021 18:13:44



US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	Ian Feather (b) (4)	22 Jan 2021 18:13:44

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Oral (ORAL)'	Ian Feather (b) (4)	22 Jan 2021 18:13:44

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	Ian Feather (b) (4)	22 Jan 2021 18:13:44

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Jan 2021'	Ian Feather (b) (4)	22 Jan 2021 18:13:44

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '0'	Ian Feather (b) (4)	22 Jan 2021 18:13:44

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'No (N)'	Ian Feather (b) (4)	22 Jan 2021 18:13:44

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '15 Jan 2021'	Ian Feather (b) (4)	22 Jan 2021 18:13:44

US3492178

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:24

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of SOLICITED ADVERSE REACTION in eDiary. Please note that this CM was given beyond Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 06:20:49
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of SOLICITED ADVERSE REACTION in eDiary. Please note that this CM was given beyond Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 16:24:44
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 16:24:31
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	17 Mar 2021 16:24:31
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of SOLICITED ADVERSE REACTION in eDiary. Please note that this CM was given beyond Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 00:19:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)'	(b) (4) Ian Feather (b) (4)	22 Jan 2021 18:13:44

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User entered empty.	System	22 Jan 2021 18:13:44

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User entered empty.	System	22 Jan 2021 18:13:44

**US3492178**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 12:27:55
User entered empty.	System	22 Jan 2021 18:13:44

US3492178

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:00:24

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Yes (Y)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:43:53
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 17:31:52

US3492178

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:00:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:44:54

US3492178

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:00:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Laparoscopic Appendectomy'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:44:54

US3492178

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:00:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:44:54

US3492178

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:00:24

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:44:54



US3492178

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:00:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:48:06

US3492178

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:00:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'CT of Abdomen'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:48:06

**US3492178**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:48:06

US3492178

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:00:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:48:06

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'USA-US101-2021-MRNA-1273-P301000003'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Yes (Y)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45



**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Yes (Y)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Richard'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Novak'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered '808 S. Wood St'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Chicago'	System	11 Jan 2021 16:52:45



**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'IL'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered '60612'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'US'	System	11 Jan 2021 16:53:31

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 15:06:10
Signature has been broken.	System	24 Feb 2021 20:33:10
User entered '4'	System	24 Feb 2021 20:33:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
	(b) (4)	
User entered '3'	System	21 Jan 2021 16:25:45
User entered '2'	System	19 Jan 2021 17:14:06
User entered '1'	System	11 Jan 2021 16:53:31

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'USA-US101-2021-MRNA-1273-P301000003'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Yes (Y)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45



**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Yes (Y)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Richard'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Novak'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered '808 S. Wood St'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Chicago'	System	11 Jan 2021 16:52:45



**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'IL'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered '60612'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'US'	System	11 Jan 2021 16:53:31

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 15:06:10
Signature has been broken.	System	24 Feb 2021 20:33:10
User entered '4'	System	24 Feb 2021 20:33:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
	(b) (4)	
User entered '3'	System	21 Jan 2021 16:25:45
User entered '2'	System	19 Jan 2021 17:14:06
User entered '1'	System	11 Jan 2021 16:53:31

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 08:00:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '11/Jan/2021 11:53'	(b) (4) System	11 Jan 2021 16:53:31

US3492178

Folder: SAE USA-US101-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:00:24

**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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'I'	(b) (4), (b) (6)	11 Jan 2021 16:53:31

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'USA-US101-2021-MRNA-1273-P301000003'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Yes (Y)'	System	11 Jan 2021 16:52:45



**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Yes (Y)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Richard'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Novak'	System	11 Jan 2021 16:52:45



**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered '808 S. Wood St'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Chicago'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'IL'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered '60612'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'US'	System	11 Jan 2021 16:53:31

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 15:06:10
Signature has been broken.	System	24 Feb 2021 20:33:10
User entered '4'	System	24 Feb 2021 20:33:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
	(b) (4)	
User entered '3'	System	21 Jan 2021 16:25:45
User entered '2'	System	19 Jan 2021 17:14:06
User entered '1'	System	11 Jan 2021 16:53:31

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 08:00:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '19/Jan/2021 17:14'	(b) (4) System	19 Jan 2021 17:14:06

US3492178

Folder: SAE USA-US101-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:00:24

**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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 16:25:50
User entered '1'	(b) (4), (b) (6)	19 Jan 2021 17:14:06



**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'USA-US101-2021-MRNA-1273-P301000003'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Yes (Y)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Yes (Y)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45



**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Richard'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Novak'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered '808 S. Wood St'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Chicago'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'IL'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered '60612'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'US'	System	11 Jan 2021 16:53:31

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 15:06:10
Signature has been broken.	System	24 Feb 2021 20:33:10
User entered '4'	System	24 Feb 2021 20:33:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
	(b) (4)	
User entered '3'	System	21 Jan 2021 16:25:45
User entered '2'	System	19 Jan 2021 17:14:06
User entered '1'	System	11 Jan 2021 16:53:31



**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 08:00:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
User entered '21/Jan/2021 11:25'	(b) (4) System	21 Jan 2021 16:25:45

US3492178

Folder: SAE USA-US101-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:00:24

**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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:25:50
User entered 'I'	(b) (4), (b) (6)	21 Jan 2021 16:25:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'USA-US101-2021-MRNA-1273-P301000003'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Yes (Y)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Yes (Y)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45



**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Richard'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Novak'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered '808 S. Wood St'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Chicago'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'IL'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered '60612'	System	11 Jan 2021 16:52:45



**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'US'	System	11 Jan 2021 16:53:31

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 15:06:10
Signature has been broken.	System	24 Feb 2021 20:33:10
User entered '4'	System	24 Feb 2021 20:33:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
	(b) (4)	
User entered '3'	System	21 Jan 2021 16:25:45
User entered '2'	System	19 Jan 2021 17:14:06
User entered '1'	System	11 Jan 2021 16:53:31

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 08:00:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '24/Feb/2021 15:33'	(b) (4) System	24 Feb 2021 20:33:10

US3492178

Folder: SAE USA-US101-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:00:24

**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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:03:35
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 20:33:10

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'USA-US101-2021-MRNA-1273-P301000003'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Yes (Y)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45



**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Yes (Y)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'No (N)'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Richard'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Novak'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered '808 S. Wood St'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'Chicago'	System	11 Jan 2021 16:52:45



**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'IL'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered '60612'	System	11 Jan 2021 16:52:45

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:57
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 17:13:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 16:57:38
User entered 'US'	System	11 Jan 2021 16:53:31

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	18 Mar 2021 15:06:10
Signature has been broken.	System	24 Feb 2021 20:33:10
User entered '4'	System	24 Feb 2021 20:33:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:57:51
	(b) (4)	
User entered '3'	System	21 Jan 2021 16:25:45
User entered '2'	System	19 Jan 2021 17:14:06
User entered '1'	System	11 Jan 2021 16:53:31

**US3492178**

**Folder: SAE USA-US101-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 08:00:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered '18/Mar/2021 11:06'	(b) (4) System	18 Mar 2021 15:06:10

US3492178

Folder: SAE USA-US101-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:00:24

**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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:48:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:48:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:06:10